Ear drops for the removal of ear wax (Review)

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[Intervention Review]

Ear drops for the removal of ear wax

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ABSTRACT

Background

Problems attributed to the accumulation of wax (cerumen) are among the most common reasons for people to present to their general practitioners with ear trouble. Treatment for this condition often involves use of a wax softening agent (cerumenolytic) to disperse the cerumen, reduce the need for, or facilitate syringing, but there is no consensus on the effectiveness of the variety of cerumenolytics in use.

Objectives

To assess the effectiveness of ear drops (cerumenolytics) for the removal of symptomatic ear wax.

Search methods

We searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, 2008 issue 2); MEDLINE; EMBASE; CINAHL; ISI Proceedings; Cambridge Scientific Abstracts; mRCT and additional sources for published and unpublished trials. The date of the most recent search was April 2008.

Selection criteria

We identified all randomised controlled trials in which a cerumenolytic was compared with no treatment, a placebo, or other cerumenolytics in participants with obstructing or impacted ear wax, and in which the proportion of participants with sufficient clearance of the external canal to make further mechanical clearance unnecessary (primary outcome measure) was stated or calculable.

Data collection and analysis

The two authors reviewed all the retrieved trials and applied the inclusion criteria independently.

Main results

Nine trials satisfied the inclusion criteria. In all, 679 participants received one of 11 different cerumenolytics. One trial compared active treatments with no treatment, three compared active treatments with water or a saline 'placebo', and all nine trials compared two or more active treatments. Eight trials included syringing as a secondary intervention.

Overall, results were inconclusive. The majority of comparisons showed no difference between treatments. Meta-analysis of two high quality trials produced a statistical difference in favour of triethanolamine polypeptide over saline in preventing the need for syringing, but no other significant differences between treatments.

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In three trials of high to moderate quality, no difference was found between the effectiveness of either sodium bicarbonate ear drops, chlorbutanol, triethanolamine polypeptide oleate condensate or docusate sodium liquid versus a sterile water or saline 'placebo'.

One trial of moderate methodological quality found all three treatments - sodium bicarbonate ear drops, chlorbutanol and sterile water - to be significantly better than no treatment at preventing the need for syringing.

None of the higher quality trials demonstrated superiority of one agent over another in direct comparisons.

Authors' conclusions

Trials have been heterogeneous and generally of low or moderate quality, making it difficult to offer any definitive recommendations on the effectiveness of cerumenolytics for the removal of symptomatic ear wax. Using drops of any sort appears to be better than no treatment, but it is uncertain if one type of drop is any better than another. Future trials should be of high methodological quality, have large sample sizes, and compare both oil-based and water-based solvents with placebo, no treatment or both.

PLAIN LANGUAGE SUMMARY

Using ear drops to remove impacted ear wax is better than no treatment, but no particular sort of drops can be recommended over any other

Impacted ear wax is one of the most common reasons that people visit their general practitioners (family doctors) with ear problems, as it can cause reduced hearing, discomfort, and sometimes pain and dizziness. Ear drops (either oil- or water-based) are often prescribed to clear the wax or to aid subsequent ear syringing if necessary. The review of trials found that ear drops (of any sort) can help to remove ear wax, but that water and saline drops appear to be as good as more costly commercial products. The quality of the trials was generally low, however, and more research is needed.

BACKGROUND

Problems attributed to the accumulation of wax are one of the most common reasons for people to present to their general practitioner (GP) with ear trouble. Ear wax removal is the most common otolaryngological procedure performed in primary care. In 1990 the average GP carried this out almost twice a week (Sharp 1990); nowadays in the United Kingdom the procedure is usually performed by nursing staff. People presenting with excessive wax in the ears therefore take up a significant proportion of GPs' consultation time.

The external auditory canal is divided into two parts, the lateral cartilaginous portion (outer two-thirds) and the medial bony portion (inner one-third). The skin lining the inner bony meatus is only 0.1 mm thick and is tightly attached to the underlying bone and to the squamo-tympanic suture. It has no special function other than protection and clearance of desquamating keratin by migration. The skin lining the outer two-thirds of the canal is 10 to 15 times thicker and has a well-developed subcutaneous layer which contains hair follicles, ceruminous glands (slightly modified sweat glands) and sebaceous glands (which open into the hair follicles). Ear wax, or cerumen, is a mixture of the secretion of these two types of glands and the exfoliated squamous epithelium (which is the major component). Cerumen also contains glycopeptides, lipids, hyaluronic acid, sialic acid, lysosomal enzymes and immunoglobulins, and exerts a protective, antibacterial effect by helping to maintain an acidic condition in the external auditory canal whilst also lubricating and protecting the ear canal (Carr 2001; Keane 1995). It has a pH of 5.2 to 7.0. Normally the wax, dust and dirt migrate in a lateral direction, the movement of the jaw contributing to this migration. The wax then passes on to the skin of the outer ear (auricle), where it dries and disappears, having achieved its aim of removing dust and destroying bacteria and fungi.

This self cleaning mechanism sometimes fails, however, causing retention or even impaction of wax. Cerumen impaction is more common in the elderly because as a person ages the cerumen glands atrophy, increasing the tendency of the cerumen to become drier. This may lead to cerumen build up and oxidation. Recent surveys examining the prevalence of impacted wax (Kalantan 1999; Lewis-Cullinan 1990; Minja 1996; Swart 1995) suggest that it is higher in men than in women, in the elderly than in the young, and in people with intellectual impairment (Brister 1990). Other factors

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that prevent the normal extrusion of wax from the ear canal (e.g. wearing a hearing aid, or using cotton buds) can further increase the chance of ear wax accumulating, while people with narrow or deformed ear canals or dermatologic disease of the periauricular skin or scalp are also susceptible to cerumen impaction.

All these factors show that the development of an occluding wax plug is not associated with personal hygiene, but is rather a constitutional and unpreventable condition. Nevertheless, a common cause of excessive cerumen accumulation remains misguided attempts to remove wax with such instruments as cotton swabs, needles and hair pins which, besides traumatising the skin, often contribute to impaction and can impair the cleansing mechanism.

Ear wax is thus a normal secretion which becomes a problem in certain circumstances. The accumulation of wax has several sequelae: (a) it can interfere with the clinician's view of the tympanic membrane; (b) it can cause a conductive hearing loss and hence may interfere with formal hearing assessment; (c) if in contact with the tympanic membrane it can cause discomfort and occasionally vertigo; and (d) it can contribute to infection (Keane 1995).

Although topical emollients have been proposed for the prevention of ear wax accumulation (Saloranta 2001), they are not widely used. However, there are a number of ways of dislodging and extracting impacted cerumen, including the use of ear syringing or irrigation (in which wax is washed out of the ear canal by a jet of warm water), other manual removal methods (such as ear curettes for hooking out the wax, or micro-suction), and two basic kinds of ear wax solvents - those based on oils which soften the wax by dissolution, and those based on aqueous systems which improve water miscibility. A combination of the above may be used. (Alternative medical therapies such as ear candling have been shown to be ineffective (Seely 1996)).

Cerumen removal is not without potential hazards. From the results of a survey of 105 general practitioners, Sharp 1990 lists specific complications of cerumen management as follows - failure of wax removal; pain; tinnitus, or vertigo; otitis media or otitis externa; damage to the skin of the external canal; and perforation of the tympanic membrane. Other complications include bleeding (which is usually self-limited), infection, or disturbance in balance causing nausea and vomiting (Dinsdale 1991; Grossan 2000; Zikk 1991; Zivic 1993). There have even been rare deaths associated with syringe irrigation (Prasad 1984), and complications occur in about 1 in 1000 ears syringed (Sharp 1990). Ear syringing is contraindicated if the ear drum is perforated, if there is a history of mastoid surgery or chronic middle ear disease, or if the person has unilateral deafness (i.e. the ear in question is the person's only hearing ear). Caution is also advised if there is a history of recurrent otitis externa or tinnitus, as it may aggravate these conditions. Thus, each of these methods of ear wax removal has potential complications, and requires a significant amount of time and effort on the part of a health care professional, who may have received little or no training for the task.

Although there is consensus that the use of cerumenolytics (with or without ear syringing) is effective, no systematic review was found examining the efficacy of this or other interventions commonly used for the treatment of impacted wax. A systematic review of published clinical trials was therefore proposed, using established meta-analysis techniques.

OBJECTIVES

To assess the clinical effectiveness of ear drops for the removal of symptomatic ear wax.

METHODS

Criteria for considering studies for this review

Types of studies

We included all identified randomised controlled trials which fulfilled the criteria outlined below. We also identified controlled clinical trials.

Types of participants

We included adults or children diagnosed as having ear wax which required removal. The need to remove the wax was determined by primary care physicians or specialists.

Types of interventions

Topical preparations including commercially produced cerumenolytics, hydrogen peroxide, olive oil or almond oil, sodium bicarbonate, water or any other topical preparation.

Types of outcome measures

Primary outcomes

- Proportion of participants with sufficient clearance of the external canal, as determined by otoscopy, to make further mechanical clearance unnecessary.

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Secondary outcomes

- Ease of mechanical removal (measured, for example, by the volume of water used to accomplish successful syringing, speed, or similar appropriate validated measures).
- Extent of wax removal.
- Proportion of people (or ears) with relief of hearing loss or discomfort.
- Proportion of people requiring further intervention to improve symptoms.

Search methods for identification of studies

We conducted systematic searches for randomised controlled trials. There were no language, publication year or publication status restrictions. The date of the last search was 23 April 2008. We searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library* 2008, issue 2); MEDLINE; EMBASE; CINAHL; BNID; LILACS; KoreaMed; IndMed; PakMediNet; Zetoc; Cambridge Scientific Abstracts; ISI Proceedings; UKCRN; UKCTG; the National Research Register (Archive); and *m*RCT (Current Controlled Trials).

We modelled subject strategies for databases on the search strategy designed for CENTRAL. Where appropriate, we combined subject strategies with adaptations of the highly sensitive search strategy designed by the Cochrane Collaboration for identifying randomised controlled trials and controlled clinical trials (as described in *The Cochrane Handbook for Systematic Reviews of Interventions* Appendix 5c (Handbook 2006)). The search terms used to search CENTRAL, MEDLINE and EMBASE are set out in Appendix 1.

One author then scanned the initial search results to identify trials which loosely met the inclusion criteria. We scanned reference lists from identified publications and contacted authors as necessary. We undertook a forward search on the authors of the identified trials.

Data collection and analysis

Selection of studies

The two authors reviewed the full text articles of all the retrieved trials of possible relevance and applied the inclusion criteria independently. We resolved any differences in opinion about which studies to include in the review by discussion.

Data extraction and management

Data from the studies were extracted by one author and rechecked by the other author. We performed data extraction using standardised forms so as to allow an intention-to-treat analysis. Where data were missing, one author wrote to the authors of the studies requesting further information.

Assessment of risk of bias in included studies

The two authors independently assessed the quality of all included trials, and resolved any differences in opinion by discussion. We used a modification of the method used by Chalmers 1990. We assessed the selected studies for the following characteristics:

1. the adequacy of the randomisation process;
2. the potential for selection bias after allocation to study group, i.e. losses to follow up and whether analysis was by intention-to-treat;
3. whether there was blinding of outcome assessors to the participants' study group;
4. quality of outcome assessment.

Studies were graded A, B or C for their overall methodological quality:

A: minimisation of bias in all four categories above, i.e. adequate randomisation; few losses to follow up and intention-to-treat analysis; blinding of outcome assessors; high quality outcome assessment.

B: each of the criteria in A partially met.

C: one or more of the criteria in A not met.

Although we intended to use study quality for sensitivity analysis, this was not appropriate in the circumstances.

Data synthesis

Where possible we analysed data to give a summary measure of effect, although most data were not comparable or of sufficient quality.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification; Characteristics of ongoing studies.

Of the 86 abstracts retrieved from our original searches in March 2003, 60 were immediately considered unsuitable for inclusion and 26 controlled trials were considered to be possibly relevant. Two of the papers were duplicate studies (Anon 1971; Masterson 2000) and two were in vitro trials (Driver 1999; Robinson 1989). Of the remaining 22 trials, five did not satisfy the inclusion criteria (Baker 1969; Hewitt 1970; Hinchcliffe 1955; Proudfoot 1968; Spiro 1997) and nine were excluded because no data addressing the primary outcome measure was either presented or extractable from the data provided (Amjad 1975; Burgess 1966; Carr 2001;

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de Saintonge 1973 Dummer 1992; Eekhof 2001; Fraser 1970; GPRG 1965; GPRG 1967), leaving eight included studies.

Of the additional 92 abstracts retrieved from our update search in April 2008, 89 were immediately considered unsuitable for inclusion. Three studies were considered possibly relevant, but on further examination two studies were excluded; Pavlidis 2005, a study examining the pre-instillation of water to facilitate syringing, because no data addressing our primary outcome measure was presented, and Roland 2004 because it measured the combined effect of cerumenolytics and irrigation. One new study from the update search was therefore included (Whatley 2003).

With the addition of one more included study to the original eight trials, we found nine trials that satisfied our inclusion criteria (Fahmy 1982a; Fahmy 1982b; Fahmy 1982c; Jaffe 1978; Keane 1995; Lyndon 1992; Meehan 2002; Singer 2000; Whatley 2003).The methods, participants, interventions and outcomes of the included studies are listed in the table 'Characteristics of included studies'. A wide range of cerumenolytics were administered in these studies, and the duration of treatment varied between one and 14 days. It was not always possible to determine accurately the dose of cerumenolytic given.

Studies are divided into three types for ease of comparison (with several studies falling into more than one category):

A: Comparison of active treatments versus no treatment;

B: Comparison of alternative active treatments versus water or saline 'placebo';

C: Head-to-head comparisons of alternative active treatments.

The studies and interventions are tabulated in Table 1.

A: Comparison of active treatment versus no treatment

Keane 1995

This double-blind, randomised controlled trial sought to determine the feasibility of significantly reducing the number of people who require ear syringing by the use of solvents, and to compare the efficacy of oil- and water-based solvents with the natural expulsion of ear wax. One hundred and thirteen geriatric inpatients with one or both ears impacted with wax were recruited; of these, 13 went home and three died during the five-day trial period (data were excluded), with 97 people (155 ears) completing the study. These participants had been randomly divided into four groups in order to receive: no treatment - 24 people (38 ears); sterile water - 24 people (38 ears) were treated with four drops of sterile water twice daily for five days; sodium bicarbonate - 25 people (39 ears) were treated with four drops of sodium bicarbonate ear drops (NaHCO3 5 g [sic], glycerol and purified water) twice daily for five days; and chlorbutanol (Cerumol®) - 24 people (40 ears) were treated with four drops of chlorbutanol (Cerumol® - ingredients: chlorbutanol 5%, turpentine oil 10%, paradichlorobenzene 2%, arachis oil 57.3%) twice daily for five days. Post-treatment, all participating ears were re-examined for the degree of impacted wax remaining and were classified as either still impacted, moderately clear, or completely clear. The desired primary outcome measure for the current review was the proportion of participants with sufficient clearance of the external canal, as determined by otoscopy, to make further mechanical clearance unnecessary. For purposes of analysis in this review, those ears 'moderately clear' or 'completely clear' were deemed to fulfil this criterion.

B: Comparison of alternative active treatments versus water or saline 'placebo'

Keane 1995

This study, described above, reported comparison of two alternative active treatments: sodium bicarbonate ear drops and chlorbutanol (Cerumol®), with sterile water.

Meehan 2002

This prospective, double-blind, randomised controlled trial compared docusate sodium (Colace®), triethanolamine polypeptide (Cerumenex®) and normal saline as cerumenolytics with and without normal saline irrigation, and sought to evaluate the role of irrigation in cerumen removal. A convenience sample of 48 children (24 males and 24 females, mean age 4.6 years) with cerumen rated as either completely or partially occluding the tympanic membrane were recruited from a university paediatric emergency department (from 2/2001 to 11/2001) and randomly divided into three groups (of 17, 15 and 16 children) to receive 1 ml of either triethanolamine polypeptide (Cerumenex®), docusate sodium (Colace®) or a control of normal saline respectively. If, after 15 minutes, the tympanic membrane was still occluded, irrigation with 50 ml of normal saline was performed and, if needed, repeated once. The outcome measure was the amount of tympanic membrane visualised, with participants re-scored as having either complete occlusion of the tympanic membrane, partial occlusion, or as being clear. Any adverse effects were recorded.

Whatley 2003

Like Meehan 2002, this prospective, randomised, double-blind study compared the cerumenolytic activity of three different solutions: docusate sodium, triethanolamine polypeptide and normal saline in 92 children aged between six months and five years with complete or partial cerumen obstruction of the tympanic membrane. Application of the drops for 15 minutes was followed, if required, by a maximum of two attempts of syringing with 50 ml of tepid tap water. The wax was identified as soft, mixed and hard and the obstruction as partial or complete depending on whether a part of the eardrum was visible on otoscopy. Thirty-four of the 92 children enrolled received docusate sodium, 30 received triethanolamine polypeptide and 28 received saline. The main outcome of the study was the proportion of tympanic membranes that were completely visualised after treatment alone or after treatment plus irrigation if necessary. The sample size of 90 was estimated to achieve 80% power to detect a 40 percentage-point difference between the treatment groups, based on the results of a previous

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study (Singer 2000).

C: Head-to-head comparisons of alternative active treatments

Jaffe 1978

This randomised, double-blind clinical trial compared the cerumenolytic effectiveness of chlorbutanol (Cerumol® - turpentine oil 10%, chlorbutanol 5%, paradichlorobenzene 2%, arachis oil 57.3%) with almond oil + arachis oil + rectified camphor oil (Otocerol®). One hundred and six people (children and adults, 0 to 89 years) with hard or impacted wax presenting at 15 general practices were recruited and randomised into two equal groups. Their degree of impaction was assessed at baseline as either mild (soft wax, which could be syringed at once if necessary), moderate (small plug of hard wax for which a cerumenolytic would usually be used before syringing), or severe (large plug of hard wax for which a cerumenolytic would be essential). The chlorbutanol group (53 people) was instructed to instil five drops daily at night into the ears for three days, and the almond oil group (53 people) to instil four drops daily at night for three days (both treatments as per manufacturers' instructions). All participants then returned for examination and syringing if necessary. Outcomes measured were the degree of impaction of wax after treatment, the necessity for syringing, and the ease of syringing where required. Neither the age, nor sex, nor degree of impaction differences between the groups were considered statistically significant by the authors. Side effects were noted.

Fahmy 1982a

This was a quasi-randomised, double-blind controlled trial examining the effectiveness of hydrogen peroxide solution (Exterol® - 5% urea hydrogen peroxide in anhydrous glycerol) for the treatment of persistent ear wax. Forty people (80 ears) with hard or impacted wax were recruited from a hospital ENT department and divided equally between test (40 ears receiving hydrogen peroxide solution (Exterol®)) and 40 ears receiving glycerol as the control. All participants were assessed for degree of wax occlusion and consistency of wax before treatment, and were then instructed to instil 5 to 10 drops into the affected ear twice daily for seven days, and to return for re-examination. The outcome measure was the ease of wax dispersal after treatment (with or without syringing).

Fahmy 1982b

Fifty people (100 ears) with impacted wax were recruited from a hospital ENT department and assessed for the degree of wax occlusion and consistency of wax before treatment. The participants were then randomly divided into two groups by alternation: one group (25 people) was treated with hydrogen peroxide solution (Exterol®) and the other group (25 people) with chlorbutanol (Cerumol®). The outcome measure was the ease of wax dispersal after treatment (with or without syringing).

Fahmy 1982c

A total of 160 people (286 ears) were recruited from five UK general practices and assessed for the degree of wax occlusion and consistency of wax before treatment. The participants were then randomly divided into two groups: the first group (157 ears) was treated with hydrogen peroxide solution (Exterol®) and the other group (129 ears) was treated with chlorbutanol (Cerumol®). The outcome measure was the ease of wax dispersal after treatment (with or without syringing).

Keane 1995

This study, described above, reported a comparison of two alternative active treatments: sodium bicarbonate ear drops (sodium bicarbonate + glycerol + water) and chlorbutanol (Cerumol®).

Lyndon 1992

Thirty-six people (19 males, mean age 52) presenting to a general practice with impacted wax in one or both ears were recruited to an open, randomised trial comparing the effectiveness of choline salicylate (Audax®) ear drops with a solution containing almond oil + arachis oil + camphor oil (Earex®). Pre-treatment examination rated the degree of wax impaction in all participants as either mild (could be syringed at once if necessary), moderate (small plug of hard wax), or severe (large plug of hard wax). The participants were then randomly divided into two groups, one (19 people, 38 ears) receiving choline salicylate solution and the other (17 people, 34 ears) receiving almond oil solution. Both groups were instructed to instil the agent twice daily for five days and then return for re-examination and one standardised syringing procedure if required. Outcomes assessed after treatment were degree of impaction and need for syringing (rated as none - syringing not required, mild, moderate, or severe), ease of syringing if required (rated as easy, difficult, or impossible), adverse effects (degree of irritation or discomfort), and global impression of efficiency of the drops by both investigator and participants (rated as completely effective, very effective, fairly effective, or not effective).

Meehan 2002

This study, described above, reported a comparison of two alternative active treatments: docusate sodium (Colace®) and triethanolamine (Cerumenex®) in children.

Singer 2000

A prospective, randomised, double-blind controlled clinical trial comparing the cerumenolytic effects of docusate sodium (Colace®) with triethanolamine polypeptide (Cerumenex®) in people with impacted cerumen. Fifty adults and children (age range 1 to 81 years, 26% children) presenting to a university-based emergency department with a medical condition requiring tympanic visualisation and with partially or totally obscured tympanic membranes were recruited. Participants were randomly divided into two groups and examined, with visualisation of the tympanic membrane classified as either partially or completely obscured. Groups were similar in age (mean = 40 years), sex (35% female), and proportion of completely obscured tympanic membranes at presentation (78%). Both groups received a single intra-aural installation in one ear only of 1 ml of either docusate sodium (27 participants) or triethanolamine polypeptide (23 participants) in liquid form.

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If not completely cleared within 15 minutes, the external ear canal was irrigated up to three times with 50 ml (100 ml on third syringing) of normal saline solution followed each time by re-examination. Adverse effects such as pain, vertigo, nausea or hearing loss were noted. The main outcome measure was the proportion of ears in which the tympanic membrane could be totally visualised after treatment instillation with or without irrigation. The authors stated that the study had 80% power to detect a 40% difference between groups in the proportion of totally visualised tympanic membranes.

Whatley 2003

This study, described above, reported a comparison of two alternative active treatments: docusate sodium versus triethanolamine polypeptide in children.

Risk of bias in included studies

All randomised controlled trials were subjected to a critical review of their methodology by the two authors and were graded for their overall methodological quality according to the stated criteria.

Methodological quality varied between studies, but was generally low with two studies scoring an A grade (Meehan 2002; Whatley 2003), two scoring B (Keane 1995; Singer 2000) and the remaining five studies scoring C (Fahmy 1982a; Fahmy 1982b; Fahmy 1982c; Jaffe 1978; Lyndon 1992).

Although all were randomised trial designs, only four described adequate randomisation and concealment procedures (Keane 1995; Meehan 2002; Singer 2000; Whatley 2003).

Studies graded A

In Meehan 2002, although no details of the randomisation method were given in the published trial, when contacted the main author recalled that a hospital pharmacist randomised the allocation by patient ID number using the Quattro-Pro randomisation programme with a Permuted Block Method, and that the test agents were concealed at the pharmacy in coloured, number-coded syringes (grade A).

In Whatley 2003, the allocation was performed by the hospital pharmacist using consecutively numbered envelopes, with the assignments generated randomly by a computerised random-number programme. There were four investigators, but prior to study commencement each investigator examined the same 26 ears and evaluated the degree of obstruction of the tympanic membrane in order to identify inter-observer variability. A k value of 0.72 was obtained, indicating (according to the study authors) a good agreement between the observers. Although this was a convenience sample of patients (and so a selection bias cannot be excluded), the study was graded A.

Studies graded B

Despite providing no details in the published trial, when contacted the author of Keane 1995 recalled that a hospital pharmacist randomised and concealed the allocation by coding, and that the treatment was administered by nurses and assessed by the investigator with the code remaining unbroken until the trial was complete. However, the data for the 16 participants who failed to complete the study were excluded and an intention-to-treat analysis was not performed by the authors.

In Singer 2000 the allocation was concealed by the hospital pharmacy in a series of opaque, consecutively numbered, 2 ml syringes, and assignments were generated by a computerised random numbers programme. However, the two solvents were visibly different in colour, which may have introduced an observer/outcome assessor bias. Furthermore, the study was a convenience sample, so a selection bias cannot be excluded whereby people with particularly hard and impacted cerumen may not have been included.

Studies graded C

Of the remaining five trials, allocation concealment was either not described or not attempted in any of them. Two of these failed to describe the randomisation method (Jaffe 1978; Lyndon 1992), while the remaining three used an inadequate method, i.e. alternate preparations given out on a sequential basis (Fahmy 1982a; Fahmy 1982b; Fahmy 1982c).

Several attempts were made to contact all the authors in order to obtain further data, and two responses were received (Keane 1995; Meehan 2002).

Six of the nine studies were double-blind, and three were unblinded (Fahmy 1982b; Fahmy 1982c; Lyndon 1992).

Effects of interventions

There was a lack of standardisation of outcome assessment across the nine included trials.

A: Comparison of active treatment versus no treatment

Only one study compared the use of active treatments with no treatment (Keane 1995).

Primary outcome measure

In this study, neither sterile water nor sodium bicarbonate + glycerol + water were found to be significantly better than no treatment for preventing the need for syringing (respectively: P = 0.06, P = 0.19). However, in the comparison of chlorbutanol (Cerumol®) versus no intervention, chlorbutanol proved to be significantly better than no treatment (P = 0.01). When the results of all of the active treatments were combined and compared with the no

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treatment group, the proportions requiring no further clearance were 62/117 and 12/38 respectively (OR 2.44, 95% CI 1.13 to 5.30).

Secondary outcome measures

No data were available from this study on the ease of mechanical removal following treatment, the proportion of participants with relief of hearing loss or discomfort, or the proportion requiring further intervention to improve symptoms. Data were available, however, on the number of ears that were completely clear versus the number moderately clear post-treatment, with all three treatments proving to be significantly better than no treatment (sterile water (P = 0.04), sodium bicarbonate + glycerol + water (P = 0.05), chlorbutanol (P = 0.03)). However, neither sodium bicarbonate + glycerol + water nor chlorbutanol performed significantly better than sterile water or each other.

B: Comparison of alternative active treatments versus water or saline 'placebo'

Three studies compared alternative active treatments with a water or saline placebo. In Keane's study of adults, all of whom had impacted wax at the start of the study, the drops were used for five days before the ears were re-assessed (Keane 1995), while in both Meehan 2002 and Whatley 2003 children with either complete or partial occlusion of the ear canal received a single instillation of ear drops followed by syringing of the ear after 15 minutes, if required.

Primary outcome measure

Keane 1995 compared both sodium bicarbonate + glycerol + water and chlorbutanol (Cerumol®) with a water placebo. Neither was found to be significantly better than water at preventing the need for syringing (respectively: P = 0.57, P = 0.51).

Data from Meehan 2002 allow comparison of docusate sodium (Colace®) with saline placebo, and triethanolamine polypeptide (Cerumenex®) with a saline placebo. After agent alone, complete visualisation of the tympanic membrane was achieved in two (13%) of the 15 patients receiving docusate sodium compared with two (12.5%) of the 16 patients receiving saline placebo (P = 0.94), and in 7 (41%) of 17 receiving triethanolamine polypeptide compared with two (12.5%) of 16 receiving saline placebo (P = 0.08), indicating that neither active agent docusate sodium nor triethanolamine polypeptide was found to be significantly better than saline. It should be recalled that not all children had completely occluded ears to start with, possibly introducing bias due to baseline differences if the proportion with only partial obstruction was different in the two groups.

Whatley 2003 also compared both docusate sodium and triethanolamine polypeptide with a saline placebo in children. Similar to Meehan's study, ears were not syringed if the tympanic membrane was completely visible after the drops, and again not all the children started with completely occluded ears. This possibly introduced a bias due to baseline differences, though some of the confounding factors were analysed. After agent alone, complete visualisation of the tympanic membrane was achieved in four (12%) of the 34 docusate sodium patients, four (13%) of the 30 triethanolamine polypeptide patients and one (4%) of the 28 saline controls (P = 0.26, P = 0.22).

Meta-analysis

As both Meehan 2002 and Whatley 2003 compared the topical cerumenolytics with saline placebo in children and were of high methodological quality (both graded A), their results were combined in a meta-analysis. Of the combined results, one was significant. In the comparison of triethanolamine polypeptide (Cerumenex®) with saline, the former proved to be significantly more effective than saline in clearing impacted cerumen sufficiently so that the syringing was unnecessary with an odds ratio (OR) of 3.77 (95% CI 1.18 to 12.04) (triethanolamine polypeptide (Cerumenex®): Figure 1; docusate sodium (Colace®): Figure 2).

Figure 1. Forest plot of comparison: 1 'Active drops' vs. saline: Triethanolamine polypeptide (Cerumenex) vs. saline in children, outcome: 1.1 Syringing not necessary.

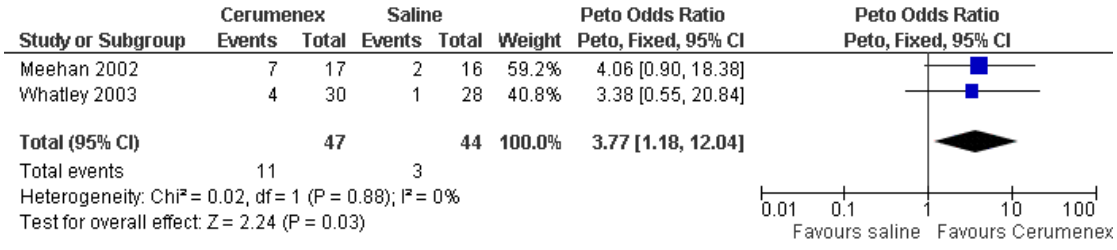

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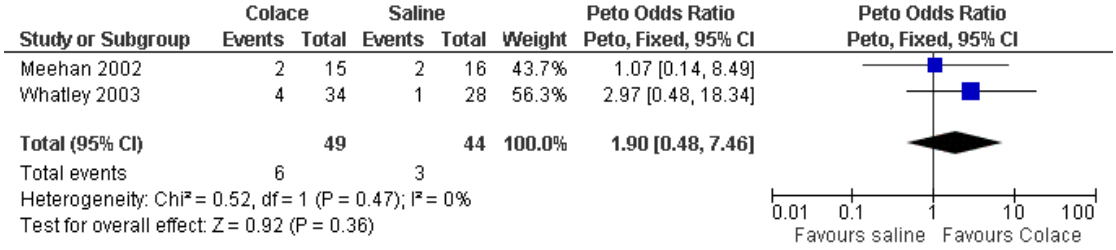
Figure 2. Forest plot of comparison: 2 'Active drops' vs saline - Docusate sodium (Colace) vs. saline in children, outcome: 2.1 Syringing not necessary.



Secondary outcome measures

No data were available from Keane's study on the ease of mechanical removal following treatment, the proportion of participants with relief of hearing loss or discomfort, or the proportion requiring further intervention to improve symptoms. Data were available on the number of ears that were completely clear versus the number moderately clear: there was no significant difference between the proportion of ears completely or moderately clear when either sodium bicarbonate + glycerol + water or Cerumol® was compared with a water placebo.

No data were available from Meehan's study on the ease of mechanical removal following treatment, the proportion of participants with relief of hearing loss or discomfort, or the proportion requiring further intervention to improve symptoms. Since the proportion of ears which at the start were completely occluded, as compared to partially occluded, varied between groups, meaningful conclusions cannot be drawn (only those ears which were completely clear were not syringed after the drops had been used). Both Meehan 2002 and Whatley 2003 report data on the effectiveness of syringing in producing 'clear' visualisation of the tympanic membrane in those participants who continued to have complete or partial obstruction after using drops. In Meehan 2002 the number of participants whose ears were cleared at the first syringing attempt after the use of triethanolamine polypeptide (Cerumenex®), docusate sodium (Colace®) or a saline placebo were one, one and four respectively. To calculate the proportion in each group the denominator ought to be the number of participants whose ears were syringed, not the number originally in each group, and this should be equal to the number originally in each group less those whose ears were completely cleared by drops alone. The numbers reported in the paper differ however, suggesting that some participants did not go on and have their ears syringed *even though* their ears were not clear as a result of the use of drops alone. To try and adhere to 'intention-to-treat' principles, we have chosen to use as the denominator the number in each group whose ears were not cleared by drops alone, that is 10, 12 and 14 respectively, giving clearance rates of syringing of 10%, 8.3% and 29% respectively; there is no significant difference between the active agents and placebo.

In Whatley 2003 after the first irrigation, complete visualisation was possible in nine of the remaining 30 unclear ears in the docusate sodium group, eight of the remaining 26 in the triethanolamine group and 11 of the remaining 27 in the saline control group. The respective proportions were 30%, 31% and 41%. None of these results indicate that either sodium docusate or triethanolaminepolypeptide was significantly better than saline. One minor adverse event was recorded (a patient with a small amount of ear canal bleeding after irrigation), but no further treatment was required and the patient was able to complete the study.

Other secondary outcomes specific to the study, such as difference in the success rates between sites, investigators and the type of wax, were not found to be significant by the study authors although the success rate was higher for the removal of soft wax (68%) than for mixed (50%) or hard wax (43%).

The results from both Meehan 2002 and Whatley 2003 were combined in a meta-analysis (triethanolamine polypeptide (Cerumenex®): Figure 3; docusate sodium (Colace®): Figure 4). Neither agent was found to be better than saline.

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Figure 3. Forest plot of comparison: 1 'Active drops' vs. saline: Triethanolamine polypeptide (Cerumenex) vs. saline in children, outcome: 1.2 Wax cleared after 1st irrigation.

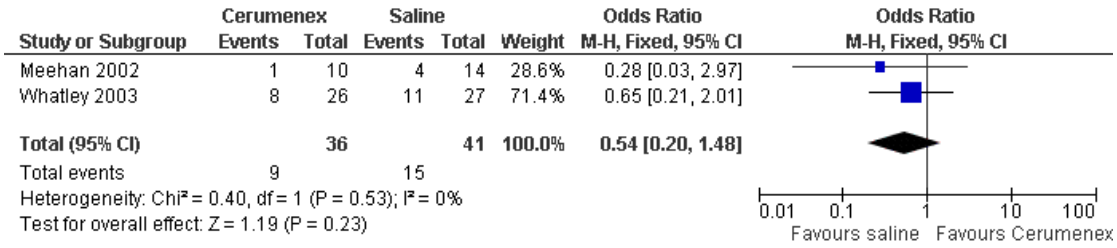
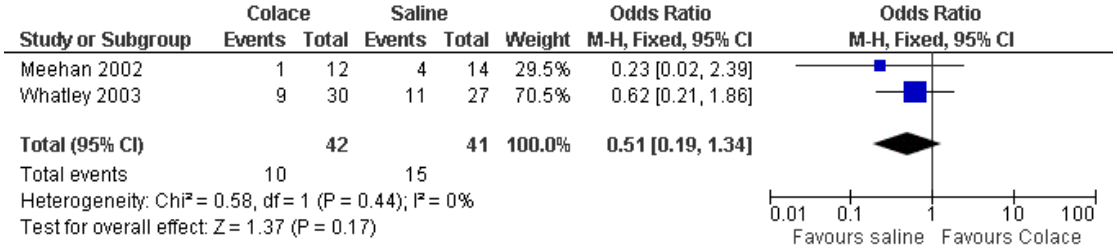


Figure 4. Forest plot of comparison: 2 'Active drops' vs saline - Docusate sodium (Colace) vs. saline in children, outcome: 2.2 Wax cleared after 1st irrigation.



C: Head-to-head comparisons of alternative active treatments

Data from several other studies allow head-to-head comparisons between alternative active treatments.

1. Chlorbutanol (Cerumol®) versus almond oil + arachis oil + rectified camphor oil (Otocerol®)

This comparison was studied by Jaffe 1978.

Primary outcome measure

Almond oil + arachis oil + rectified camphor oil (Otocerol®) was significantly better than chlorbutanol (Cerumol®) (P = 0.05) at preventing the need for syringing.

Secondary outcome measures

Jaffe assessed whether ear syringing was 'easy' or 'not easy'. Of those that needed syringing, there was no significant difference (P = 0.63) between the two treatments.

No data were available from this study on the proportion of participants with relief of hearing loss or discomfort.

2. Hydrogen peroxide (Exterol®) versus Glycerol

This comparison was studied by Fahmy (Fahmy 1982a).

Primary outcome measure

Hydrogen peroxide (Exterol®) was significantly better than glycerol (P = 0.01) at preventing the need for syringing.

Secondary outcome measures

Fahmy assessed whether ears syringed 'easily' or 'with difficulty'. Of those that needed syringing, a significantly greater proportion syringed easily with hydrogen peroxide (P = 0.001). No data were available from these studies on the proportion of participants with relief of hearing loss or discomfort.

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3. Hydrogen peroxide (Exterol®) versus chlorbutanol (Cerumol®)

Two further studies by Fahmy compared hydrogen peroxide (Exterol®) with chlorbutanol (Cerumol®) (Fahmy 1982b; Fahmy 1982c).

Primary outcome measure

Both studies demonstrated hydrogen peroxide (Exterol®) to be significantly better than chlorbutanol (Cerumol®) (Fahmy 1982b: P = < 0.01), (Fahmy 1982c: P = < 0.01).

Secondary outcome measures

As in the previous study, in both these trials Fahmy assessed whether ears syringed 'easily' or 'with difficulty'. Of those that needed syringing, a significantly greater proportion of participants in both trials syringed easily with hydrogen peroxide (Exterol®) than with chlorbutanol (Cerumol®): Fahmy 1982b: P < 0.0001; Fahmy 1982c: P = 0.0001.

No data were available from these studies on the proportion of participants with relief of hearing loss or discomfort.

4. Choline salicylate (Audax®) versus almond oil + arachis oil + camphor oil (Earex®)

This comparison was studied by Lyndon 1992.

Primary outcome measure

No significant difference was demonstrated between choline salicylate (Audax®) and almond oil + arachis oil + camphor oil (Earex®) in terms of the proportion needing syringing (P = 0.08).

Secondary outcome measures

Lyndon assessed whether ear syringing was 'easy', 'difficult' or 'impossible'. There were no cases in this last category. Of those that needed syringing, choline salicylate (Audax®) was significantly better than almond oil + arachis oil + camphor oil (Earex®) (P = 0.0009).

No data were available from this study on the proportion of participants with relief of hearing loss or discomfort.

5. Sodium bicarbonate + glycerol + water versus chlorbutanol (Cerumol®)

This comparison was made in Keane 1995.

Primary outcome measure

Keane's study fails to demonstrate any significant difference between sodium bicarbonate + glycerol + water and chlorbutanol (Cerumol®) in preventing the need for syringing (P = 0.22).

Secondary outcome measures

No data were available from this study on the ease of mechanical removal following treatment, the proportion of participants with relief of hearing loss or discomfort, or the proportion requiring further intervention to improve symptoms.

Data were available on the number of ears that were completely clear versus the number moderately clear. There was no significant difference between the proportion of ears completely or moderately clear when sodium bicarbonate + glycerol + water was compared with chlorbutanol (Cerumol®) (P = 0.65).

7. Triethanolamine polypeptide (Cerumenex®) versus docusate sodium (Colace®)

This comparison was examined in Meehan 2002, Singer 2000 and Whatley 2003. The specific features of Meehan's and Whatley's studies have been outlined above. Singer's study was undertaken in a similar setting, albeit including adults as well as children. As in Meehan 2002 and Whatley 2003, a single dose of treatment was given 15 minutes before assessment of the need for syringing.

Primary outcome measure

In Singer 2000, in both adults and children combined, no significant difference was found (P = 0.33) between docusate sodium (Colace®) and triethanolamine polypeptide (Cerumenex®) in preventing the need for syringing after a single instillation of ear drops.

In Meehan 2002 however (children only) again the difference was not significant (P = 0.09). In Whatley 2003 (children only), neither preparation performed well: the number of ears clear after application of the active agent alone were docusate sodium, four out of 34 participants (12%), compared with triethanolamine polypeptide, four out of 30 participants (13%), from which the study authors concluded that neither docusate sodium nor triethanolamine polypeptide significantly improved complete visualisation of the tympanic membrane (P = 0.85). When the data from these two A-grade paediatric studies were combined in a meta-analysis there was still no significant difference between treatments (P = 0.29) (Figure 5).

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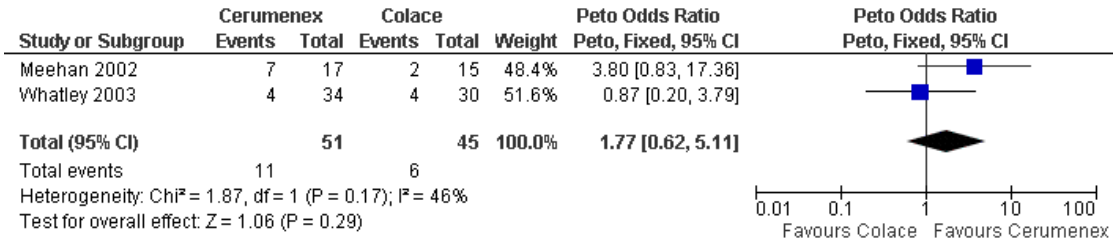
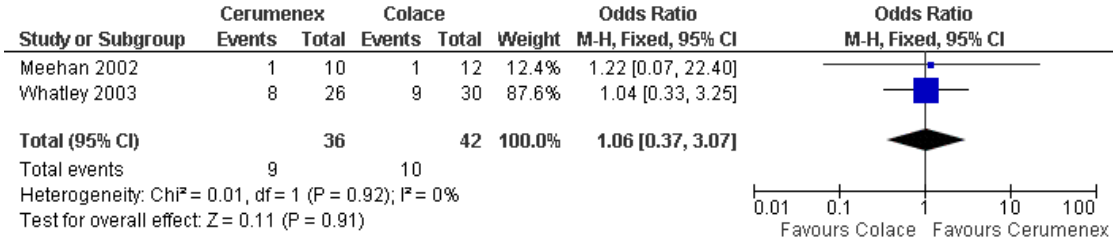
Figure 5. Forest plot of comparison: 3 Alternative 'active' drops - Triethanolamine polypeptide (Cerumenex) vs. docusate sodium (Colace)- children, outcome: 3.1 Syringing not necessary.



Secondary outcome measures

Some data on the ease (i.e. number of syringing attempts necessary) and extent (clearance rates) of wax removal can be extracted from these three studies. The data from Meehan 2002 and Whatley 2003 have been reported above together with some important comments about the denominator used in calculating the proportion of participants whose ears were cleared by syringing after the use of drops. The results from the two studies were combined in a meta-analysis. No difference was found between the two agents (Figure 6).

Figure 6. Forest plot of comparison: 3 Alternative 'active' drops - Triethanolamine polypeptide (Cerumenex) vs. docusate sodium (Colace)- children, outcome: 3.2 Wax cleared after 1st irrigation.



In Singer 2000, docusate sodium again performed better than triethanolamine polypeptide; after the first irrigation the ears of 15 of the 27 patients receiving docusate sodium were cleared compared with the ears of four of the 23 patients receiving triethanolamine polypeptide, a statistically significant difference (P = 0.008), and after the second irrigation the difference was also significant in favour of docusate sodium (P = 0.001).

Within Singer's small paediatric (< five years) population, although no data were given regarding prevention of the need for syringing, paediatric data were presented separately for irrigation post-treatment, in which docusate sodium (Colace®) appeared to perform better than triethanolamine polypeptide (Cerumenex®), although there was no statistically significant difference between the two treatments (P = 0.32). This data could not be combined within the meta-analysis as data was not given post-first irrigation.

No data were presented in any of these studies on the proportion of participants with relief of hearing loss or discomfort.

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DISCUSSION

All the included studies are in general of modest quality, and contain relatively small numbers of subjects. We took a pragmatic approach by choosing the need for syringing as a primary outcome measure, and found nine trials that addressed this issue. There was little information, however, within the included studies on the ease of syringing post-treatment: had this been the primary outcome measure more studies may have been eligible for inclusion, but perusal of the excluded studies suggests that the ways in which this outcome was measured varied considerably, and combining results from studies would again have proved difficult.

Within individual studies of good methodological quality (i.e. either grade A or B) addressing our primary outcome measure (prevention of the need for syringing), none of the comparisons showed any difference between active treatments nor between any active treatment and sterile water or saline. However, the one study which addresses our primary outcome measure and compares active treatments with no intervention suggests that using drops to remove wax may be better than nothing (Keane 1995). That is, although impacted or obstructing wax will sometimes extrude on its own, drops of any sort may enhance the process. However, it should be emphasised that this statement is based on a single trial of moderate methodological quality and with a wide confidence interval. Proprietary wax-removing agents have not been shown to be superior to saline or water.

Heterogeneity between trials meant that only limited meta-analysis could be performed, and where results from the two trials of high methodological quality (Meehan 2002; Whatley 2003, both grade A) addressing our primary outcome measure could be combined, there was only one significant difference shown - that triethanolamine polypeptide ear drops, instilled into the ears of small children for 15 minutes, proved to be better than saline at preventing the need for syringing. Whilst the point estimate of the odds ratio - about 4 - might seem favourable, the wide confidence interval (1.2 to 12) indicates that the true effect size may be very different. Meta-analysis of data addressing one of our secondary outcomes - clearance of wax post-treatment plus first syringing attempt - showed no difference between treatments.

There was no evidence presented in these studies about any harmful side effects of the agents studied. Perhaps none occurred. However, it is said, in standard texts, that some patients develop sensitivities to the constituents of some drops. Equally, it has been observed that using drops can, at least temporarily, lead to increased deafness, and if the drops are too cold when they are instilled, dizziness can result from a caloric effect on the inner ear. Syringing can produce damage to the delicate skin of the ear canal and, in some cases, perforation of the tympanic membrane. Infection may supercede in either circumstance. As a result, there is in the United Kingdom a tendency to avoid syringing and to use mechanical methods of wax removal employing suction or manipulation under direct vision.

AUTHORS' CONCLUSIONS

Implications for practice

There are no good data on which to base recommendations to use one particular cerumenolytic in preference to any other. Saline or water seems to be as effective as any proprietary agent and both have the virtue of being cheap and readily available. There is weak evidence that a short, 15-minute period of instillation of triethanolamine polypeptide ear drops, prior to syringing may be helpful.

Implications for research

Further trials of high methodological quality, with suitable sample sizes, need to be undertaken to assess the relative merits of different cerumenolytics. In particular they should compare oil-based and water-based solvents with placebo. If ease of syringing is to be used routinely as an outcome measure, some standardised method of measuring this should be agreed upon. As other mechanical methods of wax removal (for example, micro-suction) become more common in some parts of the world, the effectiveness and risks of these methods should also be rigorously evaluated.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Fahmy 1982a

Methods	Alternation, double-blind
Participants	Setting: hospital Country: UK Mean age: not known % Female: not known Duration: 7 days Number randomised: 40 participants (80 ears)
Interventions	Exterol® (5% urea hydrogen peroxide in anhydrous glycerol) versus glycerol
Outcomes	Extent of wax dispersal; ease of wax dispersal
Notes	Quality score: C

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Fahmy 1982b

Methods	Alternation, not blind
Participants	Setting: hospital ENT Department Country: UK Mean age: not known % Female: not known Duration: 7 days Number randomised: 50 participants (100 ears)
Interventions	Exterol® (5% urea hydrogen peroxide in anhydrous glycerol) versus Cerumol® (2% paradichlorobenzene, 5% chlorbutol, and 10% turpentine oil, in arachis oil base)
Outcomes	Extent of wax dispersal; ease of wax dispersal
Notes	Quality score: C

Risk of bias

Item	Authors' judgement	Description

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Fahmy 1982b (*Continued*)

Allocation concealment?	Unclear	D - Not used

Fahmy 1982c

Methods	Alternation, not blind, multicentre
Participants	Setting: general practices Country: UK Mean age: not known % Female: not known Duration: 7 days Number randomised: 160 participants (286 ears)
Interventions	Exterol® (5% urea hydrogen peroxide in anhydrous glycerol) versus Cerumol® (2% paradichlorobenzene, 5% chlorbutol, and 10% turpentine oil, in arachis oil base)
Outcomes	Extent of wax dispersal; ease of wax dispersal
Notes	Quality score: C

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Jaffe 1978

Methods	Randomised, double-blind
Participants	Setting: 15 general practices Country: UK Mean age: n/a % Female: 46 Duration: 3 days Number randomised: 106 participants
Interventions	Cerumol® versus Otocerol®
Outcomes	Impaction of wax scores; necessity for syringing; ease of syringing (where required)
Notes	Quality score: C

Risk of bias

Item	**Authors' judgement**	**Description**

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Jaffe 1978 (*Continued*)

Allocation concealment?	Unclear	D - Not used

Keane 1995

Methods	Randomised, double-blind
Participants	Setting: hospital Country: Ireland Mean age: n/a % Female: n/a Duration: 5 days Number randomised: 97 participants (155 ears)
Interventions	Cerumol® (arachis oil 57.3%, chlorbutol 5%, paradichlorobenzene 2%) versus sodium bicarbonate (NaHCO3 5g, glycerol and purified water) versus sterile water versus no treatment
Outcomes	Degree of wax removal without syringing
Notes	Quality score: B

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	A - Adequate

Lyndon 1992

Methods	Randomised, not blind
Participants	Setting: general practice Country: UK Mean age: 52 % Female: 47 Duration: 5 days Number randomised: 36 participants (72 ears)
Interventions	Audax® (choline salicylate 20%, ethyleneoxide-polyoxypropylene glycol, glycol and glycerol) versus Earex® (arachis oil, almond oil, and rectified camphor oil)
Outcomes	Degree of wax impaction and need for syringing; ease of syringing; adverse effects; global impression of efficiency
Notes	Quality score: C

Risk of bias

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Lyndon 1992 (*Continued*)

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Meehan 2002

Methods	Randomised, double-blind
Participants	Setting: university paediatric emergency department Country: USA Mean age: 3.5 % Female: n/a Duration: single treatment Number randomised: 48 children
Interventions	Colace® (docusate sodium) versus Cerumenex® (triethanolamine polypeptide) versus normal saline, with or without syringing
Outcomes	Extent of occlusion of tympanic membrane scores
Notes	Quality score: A

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Singer 2000

Methods	Randomised, double-blind
Participants	Setting: university-based emergency department Country: USA Mean age: 40 % Female: 35 Duration: single treatment Number randomised: 50 participants (50 ears)
Interventions	Colace® (docusate sodium) versus Cerumenex® (triethanolamine polypeptide) with or without syringing
Outcomes	Extent of visualisation of tympanic membrane - after treatment alone; after syringing
Notes	Quality score: B

Risk of bias

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Singer 2000 (*Continued*)

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Whatley 2003

Methods	Randomised, double-blind
Participants	Settings: urban tertiary care children's hospital emergency department and large general paediatric clinic, both in Louisville, USA
Interventions	Docusate sodium versus triethanolamine polypeptide versus saline
Outcomes	Proportion of ears achieving complete visualisation of tympanic membrane - after treatment alone; after syringing
Notes	Quality score: A

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Amjad 1975	ALLOCATION Randomised, double-blinded PARTICIPANTS 80 people (80 ears), most with hard or impacted cerumen INTERVENTIONS Cerumenex® + syringing versus carbamide peroxide + syringing OUTCOMES Primary outcome measure (assessment of extent of cerumen removal prior to syringing) not addressed
Baker 1969	ALLOCATION Non-randomised, not double-blinded nor placebo controlled PARTICIPANTS

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(*Continued*)

	51 people (88 ears) with impacted wax INTERVENTIONS Single cerumenolytic agent (Xerumenex®)
Burgess 1966	ALLOCATION Randomised, double-blinded PARTICIPANTS 50 people (74 ears) with more than one-half occlusion of an ear with wax INTERVENTIONS Dioctyl-medo® ear drops (5% dioctyl sodium sulphosuccinate in a maize oil base) + syringing versus maize oil + syringing OUTCOMES Primary outcome measure (assessment of extent of cerumen removal prior to syringing) not addressed
Carr 2001	ALLOCATION Randomised, double-blinded PARTICIPANTS 69 people with cerumen occluding at least one external auditory canal INTERVENTIONS 10% aqueous sodium bicarbonate versus 2.5% aqueous acetic acid OUTCOMES Primary outcome measure addressed, but data not usable - results given only as average change
de Saintonge 1973	ALLOCATION Randomised, double-blinded PARTICIPANTS 67 ears, unstated number of participants INTERVENTIONS Xerumenex® (triethanolamine polypeptide oleate condensate) + syringing versus olive oil + syringing OUTCOMES Primary outcome measure (assessment of extent of cerumen removal prior to syringing) not addressed
Dubow 1959	ALLOCATION Randomised, double-blinded PARTICIPANTS 60 children with at least one completely cerumen-occluded ear canal INTERVENTIONS

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(*Continued*)

	Drops (peroxide, Cerumenex® or mineral oil) plus syringing OUTCOMES Primary outcome measure (assessment of extent of cerumen removal prior to syringing) not addressed?
Dummer 1992	ALLOCATION Randomised, single-blinded (investigator) PARTICIPANTS 50 people (100 ears) with hardened or impacted ear wax INTERVENTIONS Audax® (choline salicylate and polyoxypropylene glycol condensate in glycerin and propylene glycerol) verus Cerumol® (turpentine 10%, chlorbutol 5%, paradichlorobenzene 2%, arachis oil 57.3%) OUTCOMES Primary outcome addressed, but not possible to extract necessary data
Eekhof 2001	ALLOCATION Quasi-randomised (alternation), not blinded PARTICIPANTS 42 people with persistent ear wax INTERVENTIONS Olive oil + syringing versus water + syringing OUTCOMES Primary outcome measure (assessment of extent of cerumen removal prior to syringing) not addressed
Fraser 1970	ALLOCATION Randomised, double-blinded PARTICIPANTS 62 geriatric patients with hard wax completely occluding the external auditory meatus of both ears INTERVENTIONS Cerumol® (turpentine oil 10%, chlorbutol 5%, paradichlorobenzene 2%, arachis oil 57.3%) versus sodium bicarbonate; olive oil versus sodium bicarbonate; Waxsol® (docusate sodium) versus sodium bicarbonate; Xerumenex® (triethanolamine polypeptide oleate 10% in propylene glycerol) versus sodium bicarbonate; Dioctyl® (docusate sodium in corn oil) versus sodium bicarbonate. All treatments were followed by a series of syringing attempts. OUTCOMES Primary outcome measure (assessment of extent of cerumen removal prior to syringing) not addressed
GPRG 1965	ALLOCATION Randomised, double-blinded PARTICIPANTS

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(*Continued*)

	150 people with hard or impacted cerumen INTERVENTIONS Dioctyl-medo® ear drops (5% dioctyl sodium sulphosuccinate in a maize oil base) + syringing versus maize oil + syringing OUTCOMES Primary outcome measure (assessment of extent of cerumen removal prior to syringing) not addressed
GPRG 1967	ALLOCATION Randomised, double-blinded PARTICIPANTS 107 people with hard or impacted cerumen INTERVENTIONS Waxsol® (dioctyl sodium sulphosuccinate) versus Cerumol® (turpentine oil 10%, chlorbutol 5%, paradichlorobenzene 2%, arachis oil 57.3%) + syringing versus maize oil + syringing OUTCOMES Primary outcome measure (assessment of extent of cerumen removal prior to syringing) not addressed
Hewitt 1970	ALLOCATION Randomised, not blinded PARTICIPANTS All 31 participants presented with ear pain, and majority with acute otitis media
Hinchcliffe 1955	ALLOCATION Non-randomised, double-blinded
Pavlidis 2005	ALLOCATION Randomised, non-blinded PARTICIPANTS 39 ears (of 26 patients) 'partially or completely occluded by ear wax' INTERVENTIONS Warm tap water instilled into the ear as a softening agent 15 minutes before syringing versus syringing alone OUTCOMES Primary outcome measure (assessment of extent of cerumen removal prior to syringing) not addressed
Proudfoot 1968	ALLOCATION Non-randomised, not blinded
Roland 2004	ALLOCATION Randomised, double-blinded

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(*Continued*)

	PARTICIPANTS 74 company (sponsor) employees with 'excessive or impacted cerumen' INTERVENTIONS Cerumenex® (10% triethanolamine polypeptide oleate-condensate) versus Murine® (6.5% carbamide peroxide) versus placebo (saline solution). All treatments were followed by a standardised irrigation procedure OUTCOMES Primary outcome measure (assessment of extent of cerumen removal prior to syringing) not addressed
Spiro 1997	ALLOCATION Quasi-randomised (sequential), not blinded PARTICIPANTS 302 people with hard or impacted cerumen INTERVENTIONS Colace® (docusate sodium) + syringing versus mineral oil + syringing versus no treatment + syringing versus syringing + 50% vinegar - 50% alcohol solution OUTCOMES Primary outcome measure (assessment of extent of cerumen removal prior to syringing) not addressed

Characteristics of studies awaiting assessment *[ordered by study ID]*

Caballero 2005

Methods	Randomised controlled trial
Participants	90 adults with total cerumen obstruction
Interventions	Instillation of trademarked product containing chlorobutanol or sodium carbonate, or normal saline as control 15 minutes prior to syringing
Outcomes	Proportion of the tympanic membrane visualised after irrigation
Notes	Information available from abstract only

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Characteristics of ongoing studies *[ordered by study ID]*

Schroeder 2006

Trial name or title	Controlled clinical trial of olive oil versus ear irrigation for the removal of ear wax in primary care (CLEAR)
Methods	Randomised controlled trial. Random allocation to: [A] self-administered olive oil for 21 days; [B] usual care.
Participants	The total sample size will be 330 participants, with 165 individuals in both the intervention and control groups Inclusion criteria: Participants will be included if they present with ear wax that completely occludes and obstructs the ear canal in one or both ears (with or without symptoms of, for example, blockage, irritation or loss of hearing) Exclusion criteria: partial occlusion of the ear canal (ear syringing would not be indicated); people for whom ear irrigation is contraindicated, e.g. pain, ear infection in past four weeks, pain or discharge from affected ear in past month, ear to be syringed is only hearing ear, infection, history of perforated tympanic membrane ; refusal to give informed consent ; inability to administer ear drops to external ear canal (for example those with severe joint disease)
Interventions	To investigate if the use of olive oil alone for a total of 3 weeks is as effective as usual care - i.e. olive oil for 5 days followed by ear irrigation - for the removal of ear wax in primary care
Outcomes	Primary outcomes: i) proportion of individuals with sufficient clearance of the ear canal from wax to allow visualising the ear drum of at least one ear 16 days after randomisation (which makes a total of 5 + 16 = 21 days of olive oil use) ; ii) proportion of ears with sufficient clearance of the ear canal from wax 16 days after randomisation
Starting date	01/08/2005 to 31/07/2006
Contact information	Dr K Schroeder, Academic Unit of Primary Health Care, University of Bristol, Cotham House, Cotham Hill, Bristol BS6 6JL. Telephone: +44 (0) 117 954 5508. Fax: +44 (0) 117 954 6677. E-mail: k.schroeder@bristol.ac.uk
Notes	Publication ID: N0632169201

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DATA AND ANALYSES

Comparison 1. 'Active drops' versus saline: triethanolamine polypeptide (Cerumenex) versus saline in children

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Syringing not necessary	2	91	Peto Odds Ratio (Peto, Fixed, 95% CI)	3.77 [1.18, 12.04]
2 Wax cleared after 1st irrigation	2	77	Odds Ratio (M-H, Fixed, 95% CI)	0.54 [0.20, 1.48]

Comparison 2. 'Active drops' versus saline - docusate sodium (Colace) versus saline in children

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Syringing not necessary	2	93	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.90 [0.48, 7.46]
2 Wax cleared after 1st irrigation	2	83	Odds Ratio (M-H, Fixed, 95% CI)	0.51 [0.19, 1.34]

Comparison 3. Alternative 'active' drops - triethanolamine polypeptide (Cerumenex) versus docusate sodium (Colace) - children

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Syringing not necessary	2	96	Peto Odds Ratio (Peto, Fixed, 95% CI)	1.77 [0.62, 5.11]
2 Wax cleared after 1st irrigation	2	78	Odds Ratio (M-H, Fixed, 95% CI)	1.06 [0.37, 3.07]

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Analysis 1.1. Comparison 1 'Active drops' versus saline: triethanolamine polypeptide (Cerumenex) versus saline in children, Outcome 1 Syringing not necessary.

Review: Ear drops for the removal of ear wax

Comparison: 1 'Active drops' versus saline: triethanolamine polypeptide (Cerumenex) versus saline in children

Outcome: 1 Syringing not necessary

Study or subgroup	Cerumenex n/N	Saline n/N	Peto Odds Ratio Peto,Fixed,95% CI	Weight	Peto Odds Ratio Peto,Fixed,95% CI
Meehan 2002	7/17	2/16		59.2 %	4.06 [0.90, 18.38]
Whatley 2003	4/30	1/28		40.8 %	3.38 [0.55, 20.84]
Total (95% CI)	**47**	**44**		**100.0 %**	**3.77 [1.18, 12.04]**

Total events: 11 (Cerumenex), 3 (Saline)
Heterogeneity: Chi² = 0.02, df = 1 (P = 0.88); I² =0.0%
Test for overall effect: Z = 2.24 (P = 0.025)
Test for subgroup differences: Not applicable

Analysis 1.2. Comparison 1 'Active drops' versus saline: triethanolamine polypeptide (Cerumenex) versus saline in children, Outcome 2 Wax cleared after 1st irrigation.

Review: Ear drops for the removal of ear wax

Comparison: 1 'Active drops' versus saline: triethanolamine polypeptide (Cerumenex) versus saline in children

Outcome: 2 Wax cleared after 1st irrigation

Study or subgroup	Cerumenex n/N	Saline n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Meehan 2002	1/10	4/14		28.6 %	0.28 [0.03, 2.97]
Whatley 2003	8/26	11/27		71.4 %	0.65 [0.21, 2.01]
Total (95% CI)	**36**	**41**		**100.0 %**	**0.54 [0.20, 1.48]**

Total events: 9 (Cerumenex), 15 (Saline)
Heterogeneity: Chi² = 0.40, df = 1 (P = 0.53); I² =0.0%
Test for overall effect: Z = 1.19 (P = 0.23)

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Analysis 2.1. Comparison 2 'Active drops' versus saline - docusate sodium (Colace) versus saline in children, Outcome 1 Syringing not necessary.

Review: Ear drops for the removal of ear wax

Comparison: 2 'Active drops' versus saline - docusate sodium (Colace) versus saline in children

Outcome: 1 Syringing not necessary

Study or subgroup	Colace n/N	Saline n/N	Peto Odds Ratio Peto,Fixed,95% CI	Weight	Peto Odds Ratio Peto,Fixed,95% CI
Meehan 2002	2/15	2/16		43.7 %	1.07 [0.14, 8.49]
Whatley 2003	4/34	1/28		56.3 %	2.97 [0.48, 18.34]
Total (95% CI)	**49**	**44**		**100.0 %**	**1.90 [0.48, 7.46]**

Total events: 6 (Colace), 3 (Saline)

Heterogeneity: $Chi^2 = 0.52$, df = 1 (P = 0.47); $I^2 = 0.0\%$

Test for overall effect: Z = 0.92 (P = 0.36)

Test for subgroup differences: Not applicable

Analysis 2.2. Comparison 2 'Active drops' versus saline - docusate sodium (Colace) versus saline in children, Outcome 2 Wax cleared after 1st irrigation.

Review: Ear drops for the removal of ear wax

Comparison: 2 'Active drops' versus saline - docusate sodium (Colace) versus saline in children

Outcome: 2 Wax cleared after 1st irrigation

Study or subgroup	Colace n/N	Saline n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Meehan 2002	1/12	4/14		29.5 %	0.23 [0.02, 2.39]
Whatley 2003	9/30	11/27		70.5 %	0.62 [0.21, 1.86]
Total (95% CI)	**42**	**41**		**100.0 %**	**0.51 [0.19, 1.34]**

Total events: 10 (Colace), 15 (Saline)

Heterogeneity: $Chi^2 = 0.58$, df = 1 (P = 0.44); $I^2 = 0.0\%$

Test for overall effect: Z = 1.37 (P = 0.17)

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Analysis 3.1. Comparison 3 Alternative 'active' drops - triethanolamine polypeptide (Cerumenex) versus docusate sodium (Colace) - children, Outcome 1 Syringing not necessary.

Review: Ear drops for the removal of ear wax

Comparison: 3 Alternative 'active' drops - triethanolamine polypeptide (Cerumenex) versus docusate sodium (Colace) - children

Outcome: 1 Syringing not necessary

Study or subgroup	Cerumenex n/N	Colace n/N	Peto Odds Ratio Peto,Fixed,95% CI	Weight	Peto Odds Ratio Peto,Fixed,95% CI
Meehan 2002	7/17	2/15		48.4 %	3.80 [0.83, 17.36]
Whatley 2003	4/34	4/30		51.6 %	0.87 [0.20, 3.79]
Total (95% CI)	**51**	**45**		**100.0 %**	**1.77 [0.62, 5.11]**

Total events: 11 (Cerumenex), 6 (Colace)

Heterogeneity: Chi^2 = 1.87, df = 1 (P = 0.17); I^2 =46%

Test for overall effect: Z = 1.06 (P = 0.29)

Test for subgroup differences: Not applicable

Analysis 3.2. Comparison 3 Alternative 'active' drops - triethanolamine polypeptide (Cerumenex) versus docusate sodium (Colace) - children, Outcome 2 Wax cleared after 1st irrigation.

Review: Ear drops for the removal of ear wax

Comparison: 3 Alternative 'active' drops - triethanolamine polypeptide (Cerumenex) versus docusate sodium (Colace) - children

Outcome: 2 Wax cleared after 1st irrigation

Study or subgroup	Cerumenex n/N	Colace n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Meehan 2002	1/10	1/12		12.4 %	1.22 [0.07, 22.40]
Whatley 2003	8/26	9/30		87.6 %	1.04 [0.33, 3.25]
Total (95% CI)	**36**	**42**		**100.0 %**	**1.06 [0.37, 3.07]**

Total events: 9 (Cerumenex), 10 (Colace)

Heterogeneity: Chi^2 = 0.01, df = 1 (P = 0.92); I^2 =0.0%

Test for overall effect: Z = 0.11 (P = 0.91)

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ADDITIONAL TABLES

Table 1. Studies and interventions

Comparison			Study	Grade
A: Active treatment versus no treatment				
Sterile water	vs.	Nothing	Keane 1995	B
Sodium bicarbonate	vs.	Nothing	Keane 1995	B
Chlorambutol (Cerumol®)	vs.	Nothing	Keane 1995	B
B: Active treatment versus water or saline 'placebo'				
Chlorambutol (Cerumol®)	vs.	Water	Keane 1995	B
Sodium bicarbonate	vs.	Water	Keane 1995	B
Docusate sodium (Colace®)	vs.	Saline	Meehan 2002	A
Triethanolamine (Cerumenex®)	vs.	Saline	Meehan 2002	A
Docusate sodium	vs.	Saline	Whatley 2003	A
Triethanolamine	vs.	Saline	Whatley 2003	A
C: Head-to-head comparisons of active treatments				
Chlorambutol (Cerumol®)	vs.	Almond oil (Otocerol®)	Jaffe 1978	C

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Table 1. Studies and interventions (*Continued*)

Hydrogen peroxide (Exterol®)	vs.	Glycerol	Fahmy 1982a	C
Hydrogen peroxide (Exterol®)	vs.	Chlorambutol (Cerumol®)	Fahmy 1982b	C
Hydrogen peroxide (Exterol®)	vs.	Chlorambutol (Cerumol®)	Fahmy 1982c	C
Sodium bicarbonate	vs.	Chlorambutol (Cerumol®)	Keane 1995	C
Choline salicylate (Audax®)	vs.	Almond oil (Earex®)	Lyndon 1992	B
Docusate sodium (Colace®)	vs.	Triethanolamine (Cerumenex®)	Meehan 2002	A
Docusate sodium (Colace®)	vs.	Triethanolamine (Cerumenex®)	Singer 2000	B
Docusate sodium	vs.	Triethanolamine	Whatley 2003	A

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APPENDICES

Appendix 1. Search strategies

CENTRAL	MEDLINE, EMBASE and CINAHL (Dialog DataStar)
1. CERUMEN (MeSH term) 2. CERUM* 3. (EAR* and WAX*) 4. EARWAX* OR (EAR* NEAR IMPACTED) OR (EAR* NEAR IMPACTION) 5. (#1 OR #2 OR #3 OR #4)	1. CERUMEN.DE. 2. CERUM$2.TI,AB. 3. ((EAR$1 AND WAX$1) OR (EAR$1 NEAR IMPACTED) OR (EAR$1 NEAR IMPACTION)).TI,AB. 4. EARWAX$2.TI,AB. 5. 1 OR 2 OR 3 OR 4

WHAT'S NEW

Last assessed as up-to-date: 21 April 2008.

Date	Event	Description
12 November 2008	New citation required and conclusions have changed	New searches conducted 23 April 2008. One additional new study identified (Whatley 2003). Conclusion changed following inclusion of new study.

HISTORY

Protocol first published: Issue 3, 2003

Review first published: Issue 3, 2003

Date	Event	Description
22 April 2008	Amended	Converted to new review format.
5 December 2006	New citation required and conclusions have changed	Substantive amendment.

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CONTRIBUTIONS OF AUTHORS

MARTIN BURTON: Lead author, design of review, study selection, quality assessment, analysis and interpretation of data, and writing of review.

CAROLYN DOREE: Searching for trials, study selection, data extraction, quality assessment, data analysis, and writing of review.

DECLARATIONS OF INTEREST

None known.

INDEX TERMS

Medical Subject Headings (MeSH)

Cerumen [*drug effects]; Detergents [administration & dosage]; Randomized Controlled Trials as Topic; Solvents [*administration & dosage]; Syringes

MeSH check words

Humans

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