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Non-antibiotic treatments for sore throat [Protocol]

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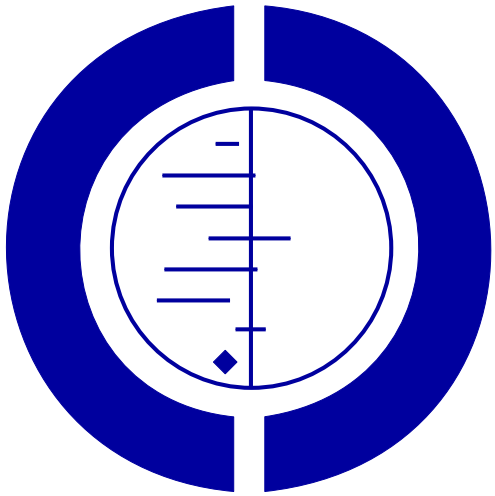

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:
1. To determine the effect of non-antibiotic treatments in the management of sore throat in children and adults.

BACKGROUND

Acute sore throats are a common reason for patients to consult general practitioners (Little 1999; Kumar 2003). Patients have traditionally been treated with antibiotics and this is still often the case (Linder 2001). A previous Cochrane review has demonstrated that antibiotics provide only a modest benefit in treating sore throat (Del Mar 2000). Most sore throats are of viral origin, are easy to manage and do not require antibiotics (Howie 1971; Little 1996; Del Mar 2000; Kumar 2003). They usually resolve within three to four days (50%) and it is unusual for the illness extend beyond one week (about 10%) (Del Mar 2000).

The traditional infective model emphasizes the importance of bacteria in the genesis of at least a proportion of cases of acute sore throat. This logically leads to the pursuit of killing bacteria to effect a cure.

Antibiotic treatment is also secondarily directed at minimizing suppurative complications (e.g. quinsy or acute otitis media) and non-suppurative ones (e.g. acute rheumatic fever) (Snellman 1993; Ebell 2000), as well as addressing symptoms (e.g. throat soreness or constitutional symptoms such as fever) and their duration (Denny 1985; Del Mar 2000).

Problems with this microbiological model include the moderately low incidence of bacteria associated with sore throat (Linder 2001), limited ability to clinical diagnose cases in which bacteria are the cause of the illness, the expense and poor performance of laboratory testing (Ebell 2000), and the limited effect of antibiotics in resolving symptoms (Del Mar 2000).

In developed countries severe complications are now so uncommon (except in high risk population groups such as Australian Aborigines) that antibiotics are not indicated (Howie 1985).

A Cochrane review of antibiotics for managing the symptoms of sore throat described a modest benefit (Del Mar 2000). A reduction in the duration of illness is greatest around day three when the mean absolute reduction is about one day (Del Mar 2000). The absolute reduction averaged over the whole illness is about 16 hours (Del Mar 2000). The use of antipyretic analgesics by participants in these studies was acceptable as this is consistent with normal practice. While not presented within this review, adverse effects such as diarrhoea, rashes and thrush are known to occur when taking antibiotics.

We wonder whether alternative treatments to antibiotics for sore throat are effective in the relief of symptoms. This review therefore aims to systematically search the evidence for non-antibiotic treatments in the management of the symptoms of sore throat, using throat pain as the preferred outcome.

A version of this systematic review has already been undertaken and published (Thomas 2000).

OBJECTIVES

1. To determine the effect of non-antibiotic treatments in the management of sore throat in children and adults.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Randomized controlled trials, in any language, which investigate any intervention other than antibiotics for acute sore throat.

Adequate randomization is defined as prospective random allocation to one of the trial groups, for example using computer generated numbers. Schemes not truly random (for example alternating patients, or alternating hospital bed numbers) will not be included.

Trials which state that they are "double-blind" but do not specify randomization are still eligible as they are assumed to be prospectively randomized. Where queries exist, authors will be contacted to request further information.

Types of participants

All patients presenting with sore throat symptoms and randomly assigned to treatment will be eligible for inclusion. Any clinically useful subgroup of "acute sore throat" will be acceptable, for example "streptococcal sore throat", as long as it is defined in the study's inclusion criteria. There will be no exclusions based on age or gender, nor will the presence of other upper respiratory infection symptoms be a cause for exclusion.

Types of intervention

Any intervention other than antibiotics used for the treatment of sore throat will be included. Examples of interventions that may be found are sprays, oral analgesics, anti-inflammatory agents and mouth washes. Interventions may be combined with antibiotics as long as both intervention and control group both received antibiotics, and the only difference between groups is a non-antibiotic intervention. No limits will be placed on the frequency of use, dose, and the duration of treatment. Control groups can include placebo or other active agents.

Types of outcome measures

Outcome measures must be symptoms of sore throat (such as soreness or associated constitutional illness), or proxies that are patient-centred. These will include the duration of illness, relapses, and complications (acute rheumatic fever, glomerulonephritis). Quality of Life measures may also be included.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Acute Respiratory Infections Group methods used in reviews.

An electronic search of a number of databases including: the Cochrane Central Register of Controlled Trials (CENTRAL) (latest issue) which contains the Acute Respiratory Infections Group's specialised register; MEDLINE (1966 to present); EMBASE (1988 to present); and HealthSTAR. The search terms to be used for the initial search of MEDLINE are as follows:

1. exp PHARYNGITIS
2. exp TONSILLITIS
3. exp COMMON COLD
4. exp RESPIRATORY TRACT INFECTIONS
5. STREPTOCOCCAL INFECTIONS
6. sore throat in TW
7. RANDOMIZED-CONTROLLED TRIAL in PT
8. RANDOMIZED-CONTROLLED-TRIALS
9. RANDOM-ALLOCATION
10. DOUBLE-BLIND-METHOD
11. SINGLE-BLIND-METHOD
12. CLINICAL-TRIAL in PT
13. explode CLINICAL-TRIALS
14. (clin* near trial*) in TI
15. (clin* near trial*) in AB
16. (singl* or doubl* or trebl* or tripl*) near (blind* or mask*)
17. (#10 in TI) or (#10 in AB)
18. PLACEBOS
19. placebo * in TI
20. placebo in AB
21. random * in TI
22. random * in AB
23. RESEARCH DESIGN
24. OR/ 7-23.
25. OR/1-6
26. #24 AND #25
27. TG=ANIMAL not (TG=HUMAN and TG=ANIMAL)
28. #26 not 27

Modifications of the above search strategy will be applied to EMBASE and HealthSTAR.

As trials are identified they will be reviewed to determine how they were indexed and the search strategy may be modified accordingly. Relevant trials and reviews will also be carefully read and reference lists examined for possible trials.

There will be no language restriction applied to the search.

Experts in the field will be contacted for any trials (regardless of whether the trial is published or unpublished). A search of any available relevant conference proceedings will also be undertaken.

METHODS OF THE REVIEW

Study Selection and Data Extraction
The search strategy will be used to identify a list of possible studies. The titles and abstract will be reviewed by two independent reviewers. Those not found to meet the inclusion criteria will be excluded. Articles are not excluded in this process will be reviewed

by the two reviewers to determine whether they meet the inclusion criteria. Disagreements will be resolved by consensus.

A checklist will be used by the reviewers who will independently extract data. Data extracted will include; author, publication year, journal, participants (numbers, duration of illness, demographics etc), intervention (dose, frequency and duration), results (outcome measures, effect, statistical significance, adverse effects) and other methodological aspects of the study (randomization process, blinding etc). Extracted information will be compared and differences resolved by consensus.

Quality Assessment
DART (Datasheet for Assessing Randomized Trials) will be used to assist quality assessment and the results will be described. Jadad's quality assessment scoring system assesses randomisation, blinding and dropouts. It scores each study between zero and five. This will be completed as part of the DART process and results reported. Two reviewers will assess each trial independently and the scores compared. Disagreements will be resolved by consensus with a third reviewer acting as a mediator if required.

Data Analysis
The studies will be stratified into categories of interventions (e.g. mouthwashes, sprays, oral analgesics and anti-inflammatory agents).

The outcome data from the studies will be examined and where possible quantitative analysis will be performed. Weighted mean difference of the change in symptom score will be calculated where appropriate. The weighted mean difference (95% confidence interval (CI)) of the final symptom score will be calculated where a baseline score is not available. The standardised mean difference may be employed where different scales are used. The relative risk or the odd's ratio, with 95% CI will be calculated for any dichotomous measures. If suitable, a meta-analysis will be conducted using a fixed effects model. If however, statistical heterogeneity calculated using a Chi-square test of N-1 degrees of freedom is found to exist (defined as $p < 0.10$), a random effects model will be used and the cause for this heterogeneity investigated.

Subgroup analysis will be performed to investigate any association between quality, population groups, and interventions and the proposed outcomes. We anticipate that there may be differences in the subgroup analyses of different age groups (child and adult), double-blinded studies and other studies, trials scoring two or above on the Jadad's score and those scoring below, differential clinical diagnoses, different treatment durations/doses, and times of measurement.

We also anticipate that there will be little consistency in the methodology used in the various trials. We will therefore place emphasis on a qualitative description of the trials results. This will outline the methodology, participants, interventions and results of the studies, including any adverse effects found to result from treatments.

If required, further information may be requested from the authors of the primary studies.

POTENTIAL CONFLICT OF INTEREST

None known.

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COVER SHEET

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Authors	Francis D, Del Mar C, Thomas M, Glasziou P
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