

Protocol for identifying parallel group RCTs within the Global Resource for Eczema Trials (GREAT) database that failed to compare the treatments being tested

Working title

How often do comparative trials in the field of eczema fail to compare the treatments being tested?

Aims

To identify the extent to which parallel group RCTs of eczema treatment that have failed to statistically compare the treatment groups.

Outcomes

Primary

- The proportion of parallel group RCTs that failed to compare the treatments being tested, from 2004 to 2013, for all reported outcomes reported in the main trial report. This will be identified by examining what is written in both the abstract and the main report.
- To examine whether comparisons are reported in the main report but not in the abstract.

Secondary

We will also extract the following information for all parallel group RCTs:

- The year of publication.
- The journal and its impact factor.
- The country that the study's corresponding author was based in.
- The funding body (Commercial/Non-commercial).

Methods

The GREAT database will be searched to identify RCTs of treatments for established eczema. The GREAT database (www.greatdatabase.org.uk) contains records of all RCTs of treatments for established eczema published since the inception of the MEDLINE (1966) and EMBASE (1980), the Cochrane Library and the Skin Group Specialised Register databases plus the CINHAL, AMED and LILACS databases from the year 2000 onwards.

A total of 302 trials published in the last decade (from 2004 to 2013) are currently listed in the database. All parallel group RCTs comparing two or more interventions will be selected. We will extract all of the outcomes listed above from the GREAT database. In order to ensure that the GREAT database captures all of the information that we require we will perform a small validation prior to extracting any data. We will review the original publications for a random sample of 10% of the trials and compare what is written to the information recorded in the GREAT database.

Analysis

Each statistician will review the trials entered in the GREAT database independently and identify those that failed to compare the treatment groups being tested. Any discrepancies between the two independent statisticians, in the identification of incorrect methods, will be resolved by a third party.

(another statistician). Once we have a list of trials that failed to compare treatment groups we will retrieve the original publications for each and explore some of the possible reasons for the lack of comparison. The results of this will be reported as a narrative discussion.

Dissemination

The target audience for this study will be anyone with an interest in eczema research. A report will be written and submitted to a peer reviewed journal, and findings will be presented at relevant academic conferences.

A lay summary of the study findings will be available on the Centre of Evidence Based Dermatology's website following publication.

The study protocol will be lodged on the Centre of Evidence Based Dermatology website (www.nottingham.ac.uk/dermatology) prior to data collection and analysis