

How are eczema symptoms captured in randomised controlled trials of eczema treatments? A systematic review protocol

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Aims

To identify and qualitatively review all outcomes that have been used in eczema treatment RCTs published from 2000 onwards that sought to capture eczema symptoms. Specifically we will assess:

Outcomes

Primary

- The number and type of eczema symptoms that have been captured in eczema treatment RCTs published from 2000 onwards and present in the GREAT database.

Secondary

- The number and type of scales / questions used to capture the symptoms
- The proportion of published RCTs on treatments for eczema included in the GREAT database that included at least one eczema symptom as an outcome measure.
- The proportion of trials that included patient-reported eczema symptoms versus investigator-reported symptoms.

Methods

The GREAT database will be searched to identify RCTs that include outcomes that include at least one eczema symptom. This may include composite scales such as SCORAD and POEM that include both symptoms and signs.

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 year 2000 onwards. However, this review will only include trials published since 2000 because data extraction, including which outcomes have been used, has only been completed for this subset of trials.

Search Strategy

The search strategy used to identify RCTs in the GREAT database is:

- MEDLINE (2000 onwards)
1. randomized controlled trial.pt.
 2. controlled clinical trial.pt.
 3. randomized.ab.
 4. placebo.ab.
 5. drug therapy.fs.
 6. randomly.ab.
 7. trial.ab.
 8. groups.ab.
 9. 6 or 3 or 7 or 2 or 8 or 1 or 4 or 5
 10. (animals not (humans and animals)).sh.
 11. 9 not 10

12. exp Dermatitis, Atopic/
13. atopic dermatitis.mp.
14. atopic eczema.mp.
15. exp NEURODERMATITIS/
16. neurodermatitis.mp.
17. infantile eczema.mp.
18. childhood eczema.mp.
19. Besniers' Prurigo.mp.
20. exp Eczema/ or eczema.mp.
21. 17 or 12 or 20 or 15 or 14 or 18 or 13 or 16 or 19
22. 11 and 21

EMBASE (2000 onwards)

1. random\$.mp.
2. factorial\$.mp.
3. (crossover\$ or cross-over\$).mp.
4. placebo\$.mp. or PLACEBO/
5. (doubl\$ adj blind\$).mp.
6. (singl\$ adj blind\$).mp.
7. (assign\$ or allocat\$).mp.
8. volunteer\$.mp. or VOLUNTEER/
9. Crossover Procedure/
10. Double Blind Procedure/
11. Randomized Controlled Trial/
12. Single Blind Procedure/
13. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
14. exp Dermatitis, Atopic/
15. atopic dermatitis.mp.
16. atopic eczema.mp.
17. exp NEURODERMATITIS/
18. neurodermatitis.mp.
19. infantile eczema.mp.
20. childhood eczema.mp.
21. (besnier\$ and prurigo).mp.
22. eczema.mp. or exp Eczema/
23. 21 or 17 or 20 or 15 or 14 or 22 or 18 or 16 or 19
24. 23 and 13

Analysis

The outcome measures identified will be summarised qualitatively and discussed.

A subsequent systematic review will be conducted to assess the validation of the outcome measures identified here.