# **Review information**

# Authors

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Citation example: DHA. NKR44 pico 6: maintenance therapy (corticosteroids) for hand eczema. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

# **Characteristics of studies**

### **Characteristics of included studies**

# Moller 1983

Methods	Study design: Randomized controlled trial Study grouping: Parallel group Open Label: Cluster RCT:
Participants	Baseline Characteristics Intervention 1 • Women (%): - • Age (SD): -
	Intervention 2 • <i>Women</i> (%): - • <i>Age</i> ( <i>SD</i> ): -
	Included criteria: Eczematous hand dermatitis which had persisted for more than 6 months in spite of attempt to identify and remove the cause. all patients had been patch tested within 2 years of initiation of the study. Excluded criteria: hand eczema with acute infection, hyperkeratotic hand eczema, hand dermatoses other than eczematois dermatoses, contact allergy to components of the topical remidies used in the study and fungal infections of the hands and/or feet. regnant or lactating women and patients in systemic immunosuppressice therapy. Pretreatment: None. Right/left hand used.
Interventions	<ul> <li>Intervention Characteristics         Intervention 1         Description: 61 patients from 14 dermatological centres. Fairly symmetrical hand eczema of at least 6 months' duration. severe/moderate/mild HE. All patiens had been using topical corticosteriods before entering the study but not for the last 2 weeks. initial healing phase with clobetasol x 2 daly op to 3 weeks. only patients where the eczematous lesions had healed intered the maintenance phase. Maintanance phase: clobetasol propionate cream on one hand (and flupredniden acetate cream on the other randomly allocated). Applied 2 x weekly. if eczema recurred during the maintenance phase, the pt was allowed to intesify treatment ( 2x daly for max 7 days). if failed to heal allowed to change to the cream used on the ofter hand, still not healed excluded from the study.         <ul> <li>Duration: Mean 138 (55-193)</li> </ul> </li> </ul>
	<ul> <li>Intervention 2</li> <li>Description: 61 patients from 14 dermatological centres. Fairly symmetrical hand eczema of at least 6 months' duration. severe/moderate/mild HE. All patiens had been using topical corticosteriods before entering the study but not for the last 2 weeks. initial healing phase with clobetasol x 2 daly op to 3 weeks. only patients where the eczematous lesions had healed intered the maintenance phase. Maintanance phase: flupredniden acetate cream on one hand (clobetasol on the other hand, randomly allocated). Applied 2 x weekly. if eczema recurred during the maintenance phase, the pt was allowed to intesify treatment ( 2x daly for max 7 days). if failed to heal allowed to change to the cream used on the ofter hand, still not healed excluded from the study.</li> <li>Duration: Mean 138 (55-193)</li> </ul>
Outcomes	Hudatrofi         • Outcome type: DichotomousOutcome         • Reporting: Fully reported         • Direction: Lower is better         • Data value: Endpoint         • Notes: atrophy, brittle skin
	<ul> <li>Flares (eksemudbrud)</li> <li>Outcome type: DichotomousOutcome</li> <li>Direction: Lower is better</li> <li>Data value: Endpoint</li> </ul>
Identification	Sponsorship source: Glaxo involved Country: Sweden Setting: Multi-center study Comments: sponsor involvement and not optimal design Authors name: Halvor Möller Institution: Department of Dermatology Email: - Address: Lund University Malmö, Sweden

### Notes

## Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no comments
Allocation concealment (selection bias)	Unclear risk	no comments
Blinding of participants and personnel (performance bias)	Low risk	Cream provided in coded samples of identical appearance except for the pairing in "left and right".
Blinding of outcome assessment (detection bias)	Low risk	The same person was also control group.
Incomplete outcome data (attrition bias)	High risk	9 patients excluded with no data
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

#### Veien 1999

Methods	Study design: Randomized controlled trial Study grouping: Parallel group Open Label: Cluster RCT:
Participants	Baseline Characteristics Intervention 1 • Women (%): NA • Age (SD): NA
	Intervention 2 • Women (%): NA • Age (SD): NA
	Control • Women (%): NA • Age (SD): NA
	Included criteria: Eczematous hand dermatitis more than 6 months in spite of attempts to identify and remove the cause. all the pt had been patch tested with the European standard patch test series within 2 years of initiation of the study. Excluded criteria: Hand czema with acute infection, hyperkeratotic hand eczema, hand dermatoses other than eczematous dermatoses, cintact allergy to components of the topical remidies used in the study and fungal infections of the and/or feet, pregnant or lactating women and patients in systemic immunosuppressive therapy. Pretreatment: The article stats that demographic data were compared to ensure that patients from the three centres and the randomization groups were comparable, but no data is available.
Interventions	Intervention Characteristics         Intervention 1         • Description: Initially the dermatitis of all the patients was treated openly for 3 weeks with one daily application of mometasone furoate (ELOCON Schering Plough, Farum Denmark) fatty cream. addetional treatment for op to 6 week if necessary. If the dermatitis had not subsided after 9 weeks of treatment the patient dropped out. Treatment whit mometasone furoate fatty cream Sunday, Tuesdays and Thursdays. Essex cream to be used freely. if recurrences occured during the maintenance phase, daily treatment with mometasone furoate was permitted for maximum of two separate periods of 3 weeks followed by the same maintenance treatment schedule as before the recurrence.
	<ul> <li>Duration: 36 weeks</li> <li>Intervention 2</li> <li>Description: Initially the dermatitis of all the patients was treated openly for 3 weeks with one daily application of mometasone furoate (ELOCON Schering Plough, Farum Denmark) fatty cream. addetional treatment for op to 6 week if necessary. If the dermatitis had not subsided after 9 weeks of treatment the patient dropped out. Treatment with mometasone furoate fatty cream on Saturdays and Sundays. Essex cream to be used freely. if recurrences occured during the maintenance phase, daily treatment with mometasone furoate was permitted for maximum of two separate periods of 3 weeks followed by the same maintenance treatment schedule as before the recurrence.</li> <li>Duration: 30 weeks</li> </ul>
	<ul> <li>Control</li> <li>Description: Initially the dermatitis of all the patients was treated openly for 3 weeks with one daily application of mometasone furoate (ELOCON Schering Plough, Farum Denmark) fatty cream. addetional treatment for op to 6 week if necessary. If the dermatitis had not subsided after 9 weeks of treatment the patient dropped out. Essex cream to be used freely as the only treatment. If recurrences occured during the maintenance phase, daily treatment with mometasone furoate was permitted for maximum of two separate periods of 3 weeks followed by the same maintenance treatment schedule as before the recurrence.</li> <li>Duration: 30 weeks</li> </ul>
Outcomes	Hudatrofi  • Outcome type: DichotomousOutcome  Flares (eksemudbrud)  • Outcome type: DichotomousOutcome
Roviow Managor	Outcome type: DichotomousOutcome

Identification	Sponsorship source: Schering-Plough A/S Farum, Denmark supplied the coded preparations for topical treatment and covered the expense of processing the data. Country: Denmark Setting: Dermatological practice Comments: Authors name: Niels Veien Institution: Hudklinikken Vesterbro 99, DK-9000 Aalborg, Danmark Email: - Address: -
Notes	<i>Tove Agner</i> on 19/03/2016 06:24 <b>Outcomes</b> outcome is also efficacy

### Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	not repported
Allocation concealment (selection bias)	Unclear risk	no clear info on how radomisation took place
Blinding of participants and personnel (performance bias)	Unclear risk	no blinding of the patient possible. No blinding of assesser is mentioned no blinding of the patient possible. No blinding of assesser is mentioned
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Low risk	14 of the 120 patients dropped out during the inital phase. 3 dropped out because their dermatitis could not be controlled (incl. in the analyse table 2, 106 patients)
Selective reporting (reporting bias)	Low risk	
Other bias	High risk	Have a potential source of bias related to the specific study design used. Patients was treated with topical corticosteroids either x3 or x2 a week or not treated. all were allowed to use Essex freely. the patients and personel seems to be able to figure out if the got the active treatment or not.

Footnotes

### **Characteristics of excluded studies**

### Clemmensen 2011

Reason for exclusion	Wrong patient population		
Jensen 2009			
Reason for exclusion	Wrong intervention		
Ramsing 1995			
Reason for exclusion	Wrong intervention		

Footnotes

## Characteristics of studies awaiting classification

Footnotes

#### **Characteristics of ongoing studies**

Footnotes

# Summary of findings tables

# **Additional tables**

# **References to studies**

#### Included studies

#### Moller 1983

Moller,H.; Svartholm,H.; Dahl,G.. Intermittent maintenance therapy in chronic hand eczema with clobetasol propionate and flupredniden acetate. Current medical research and opinion 1983;8(9):640-4. [DOI: ]

#### Veien 1999

Veien,N. K.; Olholm Larsen,P.; Thestrup-Pedersen,K.; Schou,G.. Long-term, intermittent treatment of chronic hand eczema with mometasone furoate. The British journal of dermatology 1999;140(5):882-6. [DOI: ]

#### **Excluded studies**

#### Clemmensen 2011

Clemmensen,A.; Andersen,F.; Petersen,T. K.; Hagberg,O.; Andersen,K. E.. Applicability of an exaggerated forearm wash test for efficacy testing of two corticosteroids, tacrolimus and glycerol, in topical formulations against skin irritation induced by two different irritants. Skin research and technology : official journal of International Society for Bioengineering and the Skin (ISBS) [and] International Society for Digital Imaging of Skin (ISDIS) [and] International Society for Skin Imaging (ISSI) 2011;17(1):56-62. [DOI: 10.1111/j.1600-0846.2010.00465.x [doi]]

#### Jensen 2009

Jensen, Jens-Michael; Pfeiffer, Stephan; Witt, Magdalena; Brautigam, Matthias; Neumann, Claudia; Weichenthal, Michael; Schwarz, Thomas; Folster-Holst, Regina; Proksch, Ehrhardt. Different effects of pimecrolimus and betamethasone on the skin barrier in patients with atopic dermatitis. The Journal of allergy and clinical immunology 2009;123(5):1124-33. [DOI:]

#### Ramsing 1995

Ramsing, D. W.; Agner, T.. Efficacy of topical corticosteroids on irritant skin reactions. Contact dermatitis 1995;32(5):293-7. [DOI: ]

#### Studies awaiting classification

**Ongoing studies** 

#### **Other references**

#### **Additional references**

#### Other published versions of this review

**Classification pending references** 

### **Data and analyses**

#### 1 corticosteroids 2 or 3 times weekly vs ad hoc

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Flares (eksemudbrud)	1		Risk Ratio (IV, Random, 95% CI)	Subtotals only
1.1.1 Længste follow up	1	106	Risk Ratio (IV, Random, 95% CI)	0.34 [0.22, 0.53]
1.2 Hudatrofi	1		Risk Ratio (IV, Random, 95% CI)	Subtotals only
1.2.1 Længste follow up	1	106	Risk Ratio (IV, Random, 95% CI)	5.27 [0.30, 92.73]
1.3 Livskvalitet	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable

# **Figures**

#### Figure 1 (Analysis 1.1)



Risk of blas legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias) (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)

(G) Other bias

Forest plot of comparison: 1 corticosteroids 2 or 3 times weekly vs ad hoc, outcome: 1.1 Flares (eksemudbrud).

#### Figure 2 (Analysis 1.2)



(A) Random sequence generation (selection bias)

(B) Allocation concealment (selection bias)

(C) Blinding of participants and personnel (performance bias)

(D) Blinding of outcome assessment (detection bias)

(E) Incomplete outcome data (attrition bias) (F) Selective reporting (reporting bias)

(G) Other bias

Forest plot of comparison: 1 corticosteroids 2 or 3 times weekly vs ad hoc, outcome: 1.2 Hudatrofi.