



The effect of 4% sodium cromoglicate cutaneous emulsion compared to vehicle in atopic dermatitis in children – A meta-analysis of total SCORAD scores

Michael T. Stevens & Alan M. Edwards

To cite this article: Michael T. Stevens & Alan M. Edwards (2015) The effect of 4% sodium cromoglicate cutaneous emulsion compared to vehicle in atopic dermatitis in children – A meta-analysis of total SCORAD scores, Journal of Dermatological Treatment, 26:3, 284-290, DOI: [10.3109/09546634.2014.933766](https://doi.org/10.3109/09546634.2014.933766)

To link to this article: <https://doi.org/10.3109/09546634.2014.933766>



Accepted author version posted online: 11 Jun 2014.
Published online: 18 Jul 2014.



Submit your article to this journal [↗](#)



Article views: 121



View related articles [↗](#)



View Crossmark data [↗](#)



Citing articles: 6 View citing articles [↗](#)

ORIGINAL ARTICLE

The effect of 4% sodium cromoglicate cutaneous emulsion compared to vehicle in atopic dermatitis in children – A meta-analysis of total SCORAD scores

Michael T. Stevens¹ and Alan M. Edwards²

¹EmStat Ltd., Leicester, UK and ²The David Hide Asthma and Allergy Research Centre, St Mary's Hospital, Newport, Isle of Wight, UK

Abstract

An emulsion containing 4% sodium cromoglicate (4% SCG emulsion) has been developed for the treatment of atopic dermatitis in children. We have conducted a meta-analysis of the primary outcome measure (the change in SCORAD score) used in randomized clinical trials (RCTs) with this product. We conducted a search of standard using the keywords, sodium cromoglicate, cromolyn sodium, topical, atopic dermatitis, clinical trial. We identified 19 clinical studies of which 3 used this 4% SCG emulsion formulation, one was a RCT using the change in SCORAD score. We were given access to two further unpublished RCTs, with this measure. The RCTs included 490 subjects (mean age 5.3 years). Each RCT was multicentre of 12 weeks duration, comparing 4% SCG emulsion with the vehicle in which the SCG was dissolved. Using study as the unit and the fixed effect model, the mean difference (95% CI) in the change in SCORAD score was -2.82 (-5.36 ; -0.29), $p=0.03$. Using centre as the unit, and the fixed effect model, the mean difference (95% CI) in the change in SCORAD score was -2.82 (-5.82 ; -0.46), $p=0.02$. These results support the efficacy of this new topical treatment in children with atopic dermatitis.

Keywords

Children, cromoglicate, eczema, meta-analysis, SCORAD, topical

History

Received 6 May 2014

Accepted 6 June 2014

Published online 18 July 2014

Introduction

Sodium cromoglicate is an anti-allergic, anti-inflammatory compound used in the treatment of allergic diseases. It is a topically active compound and has been used in the treatment of allergic asthma by inhalation, allergic rhinitis by intranasal spray, allergic conjunctivitis by eye-drops, food allergy by oral powder and liquids and atopic dermatitis (allergic eczema) by topical application to the skin.

A number of different topical skin formulations have been tried in the past with variable outcomes. We have conducted a meta-analysis of the change in SCORAD (1) score reported in all therapeutic trials using a new 4% sodium cromoglicate cutaneous emulsion (4% SCG emulsion) [Altocrom®, Thornton & Ross Ltd., Huddersfield, UK].

Assessment of changes in atopic dermatitis is extremely difficult, particularly in a paediatric population. It is important in measuring the treatment response in any clinical trial that validated and reliable severity scores are used (1). Of 20 severity scales used for the assessment of atopic dermatitis, only three – Scoring Atopic Dermatitis (SCORAD), Eczema Area and Severity Index (EASI) and Patient Orientated Eczema Measure (POEM) scores have been adequately validated (2). NICE guidelines conclude that SCORAD and EASI are the tools that have been validated most extensively in a research setting (3), and in the three trials included in this meta-analysis, SCORAD score was used as the primary outcome measure.

As stated in ICH E9 (3), individual clinical trials should always be large enough to satisfy their objectives but additional information may also be gained by summarizing a series of clinical trials that address essentially identical key efficacy questions. In this meta-analysis, all trials have been individually reported providing estimates of effect and the use of meta-analytic techniques to combine the estimates of effect is considered a useful addition (4). The purpose of the meta-analysis provided here is to bring together the results from studies carried out using the new 4% sodium cromoglicate cutaneous emulsion in the paediatric population in order to further assess the clinical effect compared to Vehicle and further support the results from the individual studies. A retrospective statistical analysis plan was produced and written in accordance with the EMA guideline “Points to Consider on Application with (i) Meta-analysis and (ii) One Pivotal Study” (5).

Methods

A meta-analysis involves a rigorous review of the literature to ensure all trials are considered for inclusion and justification provided for any excluded studies. We have carried out a literature search using Medline and the Cochrane Library Central Register of Controlled Trials, including the keywords, sodium cromoglicate, sodium cromoglicate, cromolyn sodium, disodium cromoglicate, topical, atopic dermatitis, atopic eczema, clinical trial, human subjects. This identified 19 clinical studies (6–24) and one review (25). Of these, only 3 studies (20,23,24) used this 4% SCG emulsion formulation and only one (20) was a clinical trial in children using the change in SCORAD score as the primary outcome measure.

Correspondence: Alan M. Edwards, Cranbrooke, Moor Lane, Brighstone, Newport, Isle of Wight, Newport PO30 4DL, UK. Tel: +44 0 1983741359. E-mail: alan.edwards@cantab.net

This formulation was originally developed by Hewlett Healthcare Ltd. (Derby, UK) and subsequently by Thornton & Ross Ltd. (Huddersfield, UK). Both authors are consultants to both organizations, who are the only ones to have been involved in providing trial material. We have therefore been made aware of all trials carried out. There are a total of six trials; three of which have been published (20,23,24). These six trials are detailed below.

Three have been excluded from this meta-analysis. The studies are detailed in the Appendix to this report. HH.Skin.P02 was an open, non-comparative study measuring systemic absorption; HH.SOT.01 was a histamine challenge study, and Cutest Study AN2629 assessed skin moisturization. None of these studies assessed SCORAD.

There have been three Phase III studies and all are included, thus no selection bias is introduced. All studies were randomized, double-blind, placebo-/vehicle-controlled trials and carried out in accordance with GCP. The three studies are identified below. Of these, the second study (T&R.SKIN.P01) also had an open, non-comparative phase following the double-blind period primarily to assess long-term safety, but only the double-blind period is considered here. The duration of the double-blind treatment period was 12 weeks in all studies. Although in the protocol titles two studies were stated as placebo-controlled and one as vehicle-controlled, the placebo and Vehicle were the same formulation, being the cutaneous emulsion without 4% sodium cromoglicate.

The three trials included in the meta-analysis are as follows: Study 1 – HH.SKIN.P01: A randomized, multi-centre, double-blind, placebo-controlled, parallel-group comparative trial to evaluate the efficacy, safety and acceptability of a topically applied lotion of sodium cromoglicate (Altoderm) in the treatment of atopic dermatitis in children (20).

Study 2 – T&R.SKIN.P01: A randomized, multi-centre, double-blind, placebo-controlled, parallel-group comparative trial to evaluate the efficacy, safety and acceptability of a topically applied lotion of sodium cromoglicate (Altoderm) in the treatment of atopic dermatitis in children (To be published).

Study 3 – 3 T&R.SKIN.P02: A multi-centre, double-blind, vehicle-controlled, randomized group-comparative study to evaluate the efficacy and safety of Altoderm, a topically applied sodium cromoglicate lotion, in the treatment of atopic dermatitis in children (To be published).

The first and last studies were carried out in similar paediatric populations, whereas the second study allowed a wider age range (1 up to 13 years compared to 2 up to 12 years) and greater severity for atopic dermatitis on entry (Total SCORAD ≥ 25 compared to 25–60).

Dryness of the skin is one of the elements of disease intensity recorded in the SCORAD score. At the end of the baseline period, skin dryness was more severe in the second study with 64% scoring 2 or 3 on a 0–3 scale (where 0 is no dryness and 3 is severe dryness) and 30 subjects scoring 3, compared to only 37% in the first study with 1 subject scoring 3. The third study also had less severity of dryness at randomization than the second study with only 5% scoring a grade of 3. Clinically, the greater severity of dryness would tend to exaggerate the emollient response. The second study also allowed calcineurin inhibitors and wet wrapping as concomitant therapy in addition to emollients and topical steroids.

After reviewing, the results of the first two studies, the third study was designed as closely as possible to the first study. Since assessments of atopic dermatitis in children may be highly dependent on study design, some heterogeneity in response may be encountered and therefore the meta-analysis was carried out including all three studies and also on the two most similarly designed studies 1 & 3.

The primary variable in all studies was the Total SCORAD score as assessed at each visit. In particular, the end of study visit in all studies was considered the primary time-point. The meta-analysis is restricted to the analysis of the Total SCORAD score at the end of the study (specifically the change from baseline at 12 weeks treatment) and since this was clearly defined as primary in all three studies, there is no bias due to selection of endpoint.

The objective of this meta-analysis was to provide an overall estimate of the effect of SCG compared to Vehicle. The data used in the analyses are that pertaining to the Full Analysis Set (FAS).

Consideration should be given to the unit for the meta-analysis. Typically, this is taken as “study”. Using study as the unit, it is known that some degree of heterogeneity will be present since the second study failed to confirm the results of the first study due mainly to a large response in the Vehicle group as well as the 4% SCG emulsion group and possibly due to differences in design. Indeed, this was the reason for carrying out a third study, following as closely as possible the design of the first study. A meta-analysis using “study” as the unit has been carried out using a fixed effect model, since the small number of studies precludes a good estimate of between-study variation being obtained.

However, as each study was itself a multi-centre study, the unit could be taken as “centre” (more precisely “centre grouping” as used in the individual study analyses) for the meta-analysis. It should be recognized however that centres within a study may be more closely related than centres from different studies. A meta-analysis using “centre grouping” for consistency with the individual study reports as the unit has also been carried out using both a fixed effect model and a random effect model. A fixed effect model assumes the treatment effect is constant across centres, whereas the random effect model allows the effect to vary from centre to centre.

The meta-analyses were carried out using data from the study reports and the Cochrane Collaboration software “Review Manager” (26). Outputs are obtained directly from Review Manager and consist of the mean, SD, *n* for each treatment by study/centre grouping; the mean difference between treatments with 95% CI by study/centre grouping; the overall estimated difference between treatments with 95% CI; together with tests for heterogeneity and overall treatment effect. Plots of differences between treatments and 95% CI are also provided.

Results

As indicated above, all three studies were of a double-blind, randomized, parallel group design. The duration of the double-blind treatment period was 12 weeks. The main characteristics of the studies are shown in Table 1.

From Table 1, it can be seen that due to the different entry criteria, the age range for Study 2 was wider than Study 1, and the mean Total SCORAD score was higher. The main contributor to the higher SCORAD was the dryness severity which was more severe in Study 2 than Study 1. Thus, Study 3 was designed to be as similar to Study 1 as possible, with emollient being used throughout the baseline which was extended to 4 weeks to allow a clearer definition of SCORAD including the assessment of dryness with emollient use.

The assessment of Total SCORAD reported below is based on 490 subjects (275 4% SCG emulsion, 215 Vehicle) with evaluable data in the Full Analysis Set (FAS) population as reported in the individual reports.

By study analyses

Results of the analyses using study as the unit are given in Table 2, which includes all three studies and the full output is

Table 1. Study characteristics.

Characteristic	Study 1 (HH.SKIN.P01)	Study 2 (T&R.SKIN.P01)	Study 3 (T&R.SKIN.P02)
No. of subjects (safety population)	114	177	206
Length of baseline (weeks)	2	2	4
Con meds allowed	Emollients Topical steroids	Emollients Topical steroids Calcineurin inhibitors Wet wrapping	Emollients Topical steroids
Gender			
Male	68 (59.6%)	94 (53.1%)	100 (48.5%)
Female	46 (40.4%)	83 (46.9%)	106 (51.5%)
Age (years)			
Mean	5.5	5.2	5.3
Range	1.8, 11.9	1.0, 12.8	2.0, 11.0
Total SCORAD at randomization			
Mean	40.7	46.2	40.8
Range	25.0, 60.5	25.2, 92.4	25.0, 65.0
Severity of dryness at randomization ^a			
0	16 (14.0%)	6 (3.4%)	8 (3.9%)
1	56 (49.1%)	58 (32.8%)	69 (33.5%)
2	41 (36.0%)	83 (46.9%)	119 (57.8%)
3	1 (0.9%)	30 (16.9%)	10 (4.8%)
No. of centres	4	15	13
No. of centre groupings	4	5	8
No. of subjects (FAS population)	114	177	199

^aScoring system for dryness 0 = none, 1 = mild, 2 = moderate, 3 = severe.

Table 2. By study analyses – three studies (FAS).

Outcome	Fixed effect		
	Effect ^a (95% CI)	<i>p</i> value	Hetero. <i>p</i> value
SCORAD	−2.82 (−5.36, −0.29)	0.03	0.06

^aEffect is difference between treatments.

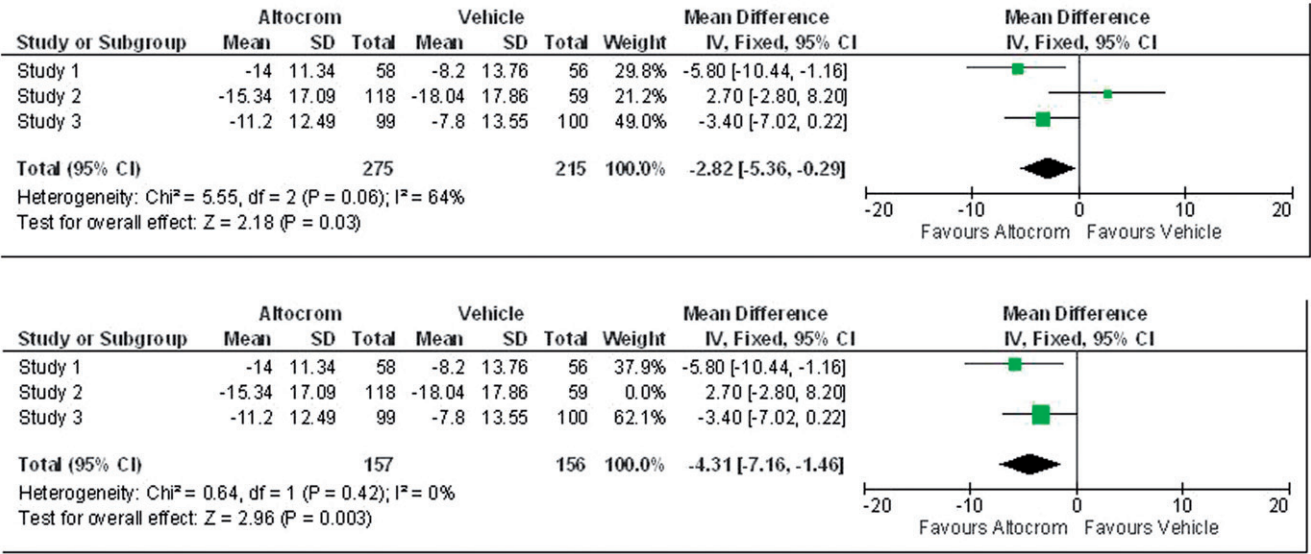


Figure 1. Outputs from meta-analyses (FAS population) – change in total SCORAD. (A) By study: all studies – fixed effect. (B) By study excluding study 2 – fixed effect.

shown in Figure 1(A). Due to the small number of studies, only the fixed effect analysis is given. As expected, there is a significant degree of heterogeneity, due to the results from Study 2. However, the “average” effect was statistically significant for SCORAD ($p = 0.03$).

Since Study 2 was clearly the contributor to heterogeneity, the analyses were repeated excluding Study 2 and the results are provided in Table 3, and the full output is shown in Figure 1(B). The results indicate a much clearer homogeneity of response across the two studies, with statistically significant

Table 3. By study analyses excluding study 2 (FAS).

Outcome	Fixed effect		
	Effect ^a (95% CI)	<i>p</i> value	Hetero. <i>p</i> value
SCORAD	-4.31 (-7.16, -1.46)	0.003	0.42

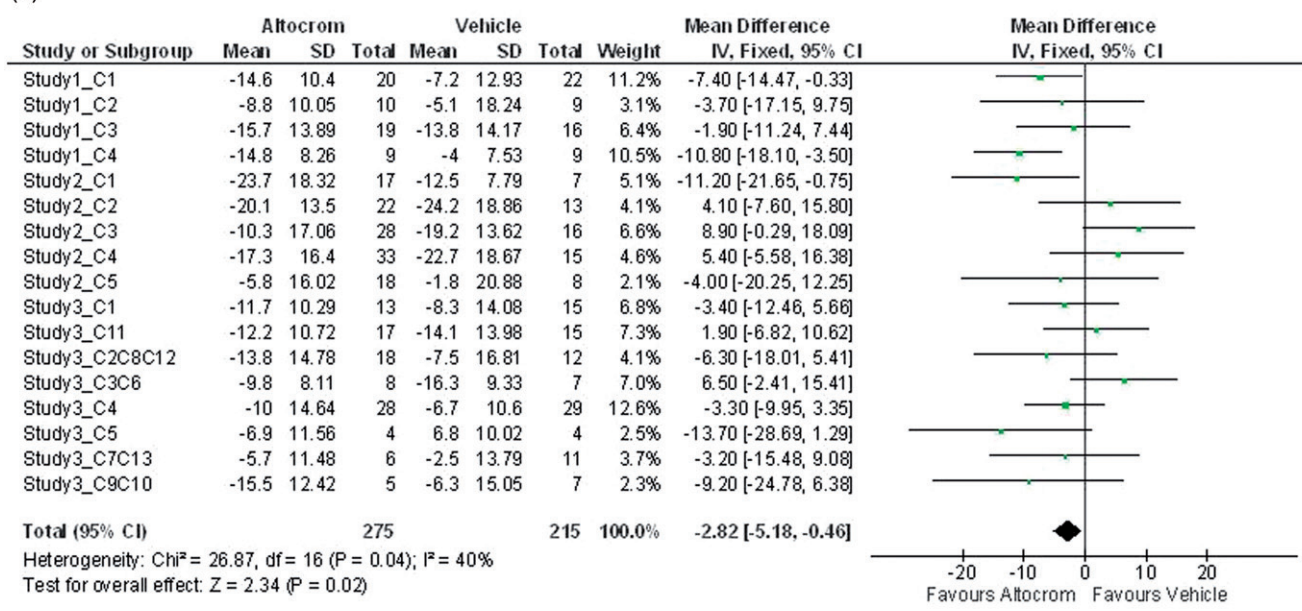
^aEffect is difference for SCORAD.

Table 4. By centre analyses – three studies (FAS).

Outcome	Fixed effect			Random effect		
	Effect ^a (95% CI)	<i>p</i> value	Hetero. <i>p</i> value	Effect (95% CI)	<i>p</i> value	Hetero. <i>p</i> value
SCORAD	-2.82 (-5.18, -0.46)	0.02	0.04	-2.69 (-5.86, 0.48)	0.10	0.04

^aEffect is difference between treatments.

(A)



(B)

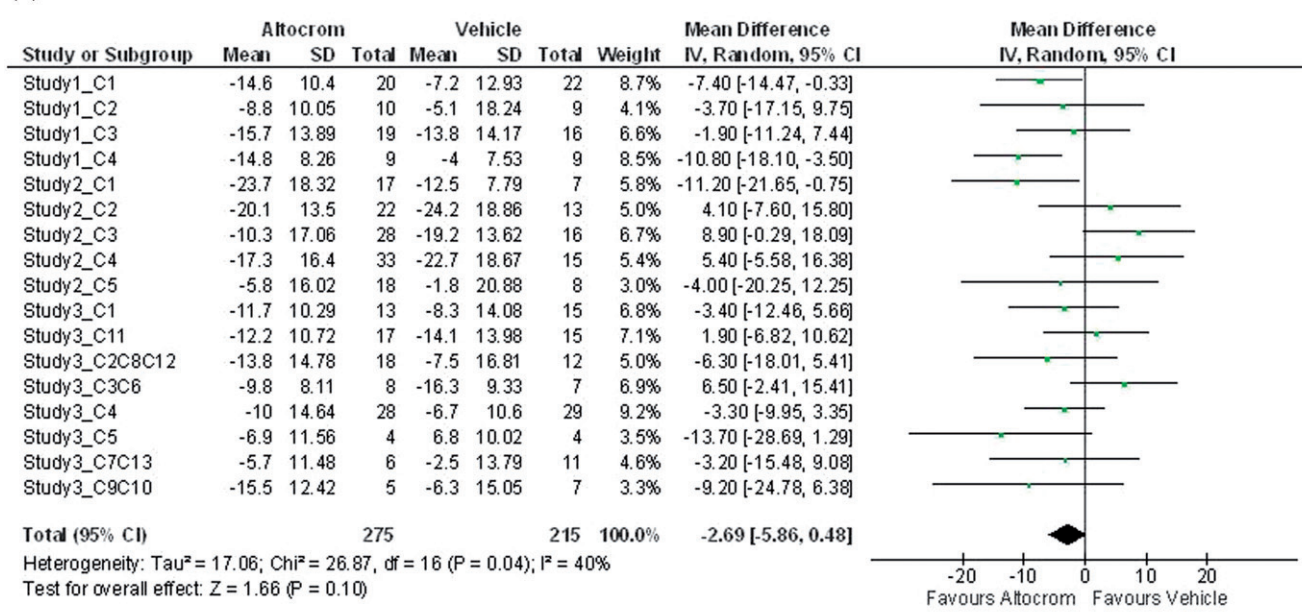


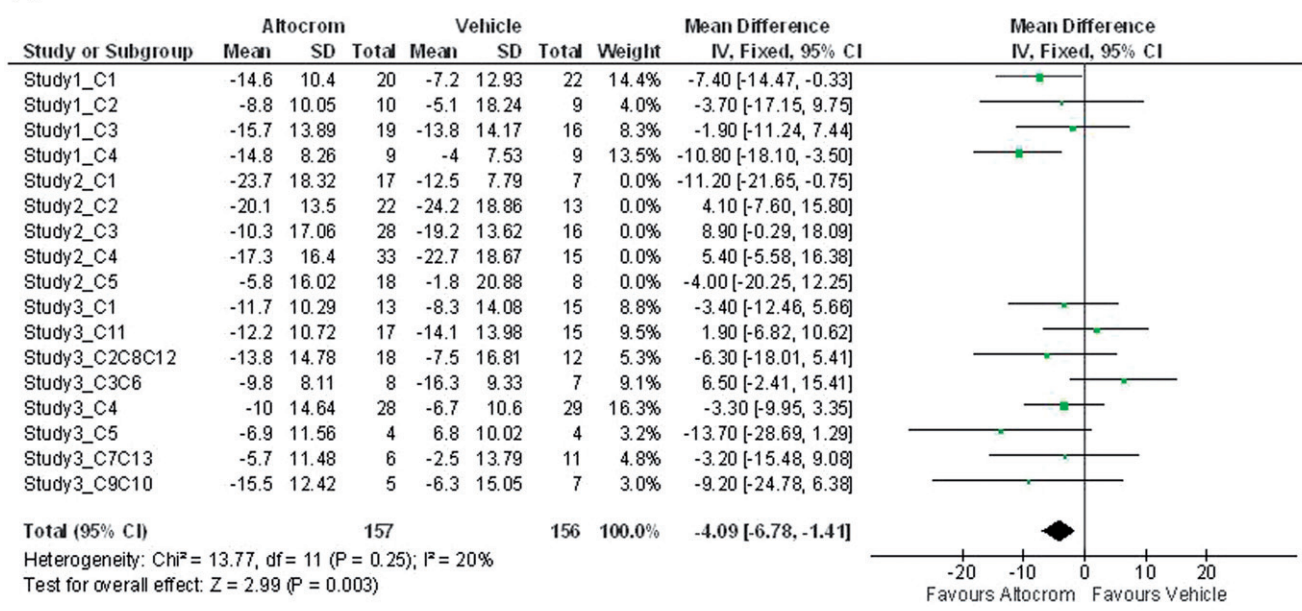
Figure 2. Outputs from meta-analyses (FAS population) – change in total SCORAD. (A) By centre: all studies – fixed effect. (B) By centre: all centres – random effect.

Table 5. By centre analyses excluding study 2 (FAS).

Outcome	Fixed effect			Random effect		
	Effect ^a (95% CI)	<i>p</i> value	Hetero. <i>p</i> value	Effect (95% CI)	<i>p</i> value	Hetero. <i>p</i> value
SCORAD	-4.09 (-6.78, -1.41)	0.003	0.25	-4.05 (-7.13, -0.97)	0.01	0.25

^aEffect is difference between treatments.

(A)



(B)

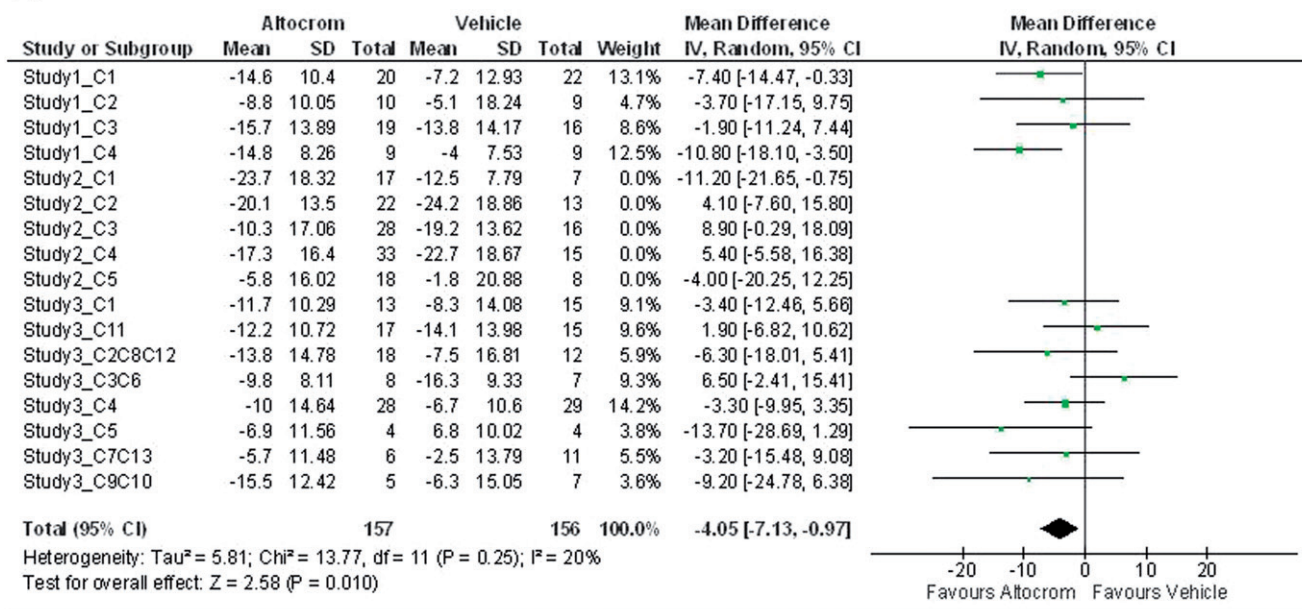


Figure 3. Outputs from meta-analyses (FAS population) – change in total SCORAD. (A) By centre excluding study 2 – fixed effect. (B) By centre excluding study 2 – random effect.

The full outputs are shown in Figure 2(A and B), respectively. There is a significant degree of heterogeneity for SCORAD. However, the “average” effect was statistically significant for SCORAD ($p=0.02$) using the fixed effect model and approached significance using the random effect model ($p=0.10$).

Since Study 2 was clearly the contributor to heterogeneity, the analyses were repeated excluding Study 2 and the results are provided in Table 5. The full outputs are shown in Figure 3(A and B), respectively. The results indicate a much clearer homogeneity of response across the two studies, with statistically significant effects in favour of Altoderm being seen for SCORAD

($p=0.003$) for the fixed effect model and the random effect model ($p=0.01$).

Discussion

Three therapeutic studies have been completed evaluating 4% SCG emulsion versus Vehicle in double-blind randomized, parallel group studies. A total of 490 subjects were included in the assessment of Total SCORAD (275 4% SCG emulsion, 215 Vehicle). In all studies, the primary variable was the change from baseline in total SCORAD score at the end of the study, all of which were of 12 weeks duration of treatment. Study 1 demonstrated a statistically significant difference in favour of 4% SCG emulsion. No significant difference was detected between treatments in Study 2 in which both treatments showed a marked response compared to baseline. Study 3 again showed statistically significant benefits in favour of 4% SCG emulsion during the study, although the difference just failed to reach statistical significance after 12 weeks ($0.05 < p < 0.10$). In all three studies, the change in SCORAD score within both treatment groups was highly statistically significant, demonstrating that both treatments are effective in the treatment of atopic dermatitis. The two treatments differ only by the addition of 4% sodium cromoglicate. This meta-analysis shows that the addition of 4% SCG to the vehicle produces a significantly greater effect, confirming it is the more effective treatment.

Study 2 was identified as enrolling more severe subjects with considerably more severe dryness than Study 1. Clinically, severity of dryness may be associated with an enhanced effect of emollients and hence reduce the differential between treatments and this may explain the heterogeneity in response. The Cutest study included in Appendix 2 showed that the placebo/vehicle increases the moisturization of the skin whereas the 4% SCG emulsion does not. The placebo/vehicle is therefore an effective treatment itself but the 4% SCG emulsion is more effective.

The analyses presented include all three studies and also an analysis excluding Study 2, Study 1 and 3 being the most similar protocols. Analyses have been carried out using study as the unit for analysis and also the centre groupings as presented in the individual study reports. This provides a sensitivity analysis. Additionally, fixed and where appropriate random effect models are evaluated. The results are consistent across all analyses in demonstrating statistically significant differences ($p < 0.05$) in favour of 4% emulsion compared to Vehicle in all but one analysis ($p = 0.10$).

Conclusion

This report presents the meta-analyses of three therapeutic studies involving 4% SCG emulsion (490 subjects in the FAS population). The primary variable in all studies was change from baseline in total SCORAD score at the end of treatment. The results from this meta-analysis support the results of the individual studies and demonstrate that this formulation of sodium cromoglicate is an effective treatment for atopic dermatitis in children.

Declarations of interest

Both authors are consultants to the manufacturers of this formulation of topical sodium cromoglicate, Thornton & Ross Ltd.

References

1. Staider JF, Taieb A. Severity scoring of atopic dermatitis: the SCORAD index. Consensus Report of the European Task Force on Atopic Dermatitis. *Dermatology*. 1993;186:23–31.
2. McAleer MA, Flohr C, Irvine AD. Management of difficult and severe eczema in childhood. *BMJ*. 2012;345:e770.

3. National Institute for Health and Care Excellence. (Atopic Dermatitis in Children) [CG57]. London: National Institute for Health & Care Excellence, 2007.
4. European Medicines Agency. Statistical Principles for Clinical Trials. CPMP/ICH/363/96, 1998.
5. European Medicines Agency. Points to consider on Application with 1. Meta-analyses. 2. One Pivotal Study. CPMP/EWP/2330/99, 2001.
6. Haider SA. Treatment of atopic eczema in children A clinical trial of 10% SCG ointment. *BMJ*. 1977;1:1570–2.
7. Thirumoothy T, Greaves MW. Disodium cromoglycate ointment in atopic eczema. *BMJ*. 1978;2:500–1.
8. Haider SA. Treatment of atopic dermatitis in children: use of topical sodium cromoglycate. In Pepys J, Edwards AM, eds. *The Mast Cell: Its Role in Health and Disease*. Tunbridge Wells. Kent: Pitman Medical, 1979. p 570–6.
9. Zachariae H, Afzelius H, Lauberg G. Topically applied sodium cromoglycate in atopic dermatitis. In Pepys J, Edwards AM, eds. *The Mast Cell: Its Role in Health and Disease*. Tunbridge Wells. Kent: Pitman Medical, 1979. p 568–9.
10. Zachariae H, Thestrup-Pedersen K, Thulin H, et al. Experimental treatment in atopic dermatitis: immunological background and preliminary results. *Acta Dermatovenereol (Stockholm) Suppl*. 1980; 92:121–7.
11. Croner S, Fagerlund L, Kjellman NI. Sodium cromoglycate ointment in atopic eczema during childhood. *Opuscula Med*. 1981;26:49–50.
12. Ariyanayagam M, Barlow TJG, Graham P, et al. Topical sodium cromoglycate in the management of atopic eczema – a controlled trial. *Br J Dermatol*. 1985;112:343–8.
13. Kjellman N-IM, Gustafsson IM. Topical sodium cromoglycate in atopic dermatitis. *Allergy*. 1986;44:423–8.
14. Nagano T. Topical use of disodium cromoglycate nebulizer solution in adults with severe atopic dermatitis. *Allergy Pract*. 1987;7:790–3.
15. Pike MG, Atherton DJ. Failure of a new topical sodium cromoglycate formulation to improve atopic dermatitis. *Eur J Pediatr*. 1988; 148:170–20.
16. Kimata H, Igarashi MIE. Topical cromolyn (disodium cromoglycate) solution in the treatment of young children with atopic dermatitis. *Clin Exp Allergy*. 1990;20:281–3.
17. Kimata H, Hiratsuka S. Effect of topical sodium cromoglycate solution on atopic dermatitis: combined treatment of sodium cromoglycate solution with the oral anti-allergic medication, oxatomide. *Eur J Pediatr*. 1994;153:66–71.
18. Hiratsuka S, Yoshida A, Ishioka C, Kimata H. Enhancement of in vitro spontaneous IgE production by topical steroids in patients with atopic dermatitis. *J Allergy Clin Immunol*. 1996;98: 107–13.
19. Moore C, Ehlayel MS, Junprasert J, Sorensen RU. Topical sodium cromoglycate in the treatment of moderate to severe atopic dermatitis. *Ann Allergy Asthma Immunol*. 1998;81: 452–8.
20. Stainer R, Matthews S, Arshad SH, et al. Efficacy of a new topical skin lotion of sodium cromoglycate (Altoderm) in atopic dermatitis in children aged 2–12 years: a double-blind, randomized, placebo-controlled trial. *Br J Dermatol*. 2005;152:334–41.
21. Lopez X, Castells M, Ricker A, et al. Human insulin analog-induced lipotrophy. *Diabetes Care*. 2008;31:442–4.
22. Vieira Dos Santos R, Magerl M, Martus P, et al. Topical sodium cromoglycate relieves allergen- and histamine-induced dermal pruritus. *Br J Dermatol*. 2010;162:674–6.
23. Edwards AM, Matthews S, Arshad SH. Systemic absorption of sodium cromoglycate from a new cutaneous emulsion (Altoderm®) in children with atopic dermatitis. *Eur J Dermatol*. 2010;20:864–5.
24. Edwards AM, Stevens MT, Church MK. The effects of topical sodium cromoglycate on itch and flare in human skin induced by intradermal histamine: a randomised double-blind vehicle controlled intra-subject design trial. *BMC Res Notes*. 2011;4:47.
25. Zur E. Topical use of sodium cromoglycate (cromolyn sodium) to treat atopic dermatitis and other skin allergies. *Int J Pharm Compd*. 2012;16:386–93.
26. The Cochrane Collaboration 2008. Review Manager Version 5.1.0. Copenhagen: The Nordic Cochrane Centre.

Appendix

Trials not included in meta-analysis

HH.Skin.P02

Systemic absorption of sodium cromoglicate from a new cutaneous emulsion (Altoderm) in children with atopic dermatitis.

An open study during which nine subjects (eight children, one adult) who had been using Altoderm for at least 3 months as a treatment for atopic dermatitis, collected a 24-h urine specimen during a 6-day period using Altoderm twice daily. Mean absorption was $1.46 \pm 0.91\%$ of amount applied. Ref. Edwards AM, Matthews S, Arshad SY. Systemic absorption of sodium cromoglicate from a new cutaneous emulsion (Altoderm) in children with atopic dermatitis. *Eur J Dermatol.* 2010;20; Correspondence 1–2.

HH.SOT.01

A randomized, double-blind, vehicle-controlled intra-subject design trial to determine the effects of Altoderm on itch and flare in human skin induced by intra-dermal histamine.

After topical application of three concentrations of sodium cromoglicate, 1%, 2% and 4% and vehicle, healthy subjects (both atopic and non-atopic), were challenged with intradermal injections of histamine.

The itch and flare reactions were significantly reduced in atopic subjects. Trend analysis showed increasing effect on itch with increased concentrations of sodium cromoglicate. Ref. Edwards AM, Stevens MT, Church MK. The effects of topical sodium cromoglicate on itch and flare in human skin induced by intradermal histamine: a randomised double-blind vehicle controlled intra-subject design trial. *BMC Res Notes* 2011;4:47.

Cutest study AN2629

To determine the effect of four topical formulations on skin moisturization as assessed by the Corneometer and transepidermal water loss as measured by the Tewameter. Twenty healthy volunteers 4 topical formulations to designated test sites on their forearms. Skin capacitance measurements were taken on sites of application and control (untreated) sites at –30, –15, 0, +20, +40, +60 and +90 min after application. The four formulations were: (1) a cooling gel, (2) aqueous cream BP, (3) modified aqueous cream = vehicle for altoderm and (4) modified aqueous cream + 4% sodium cromoglicate = altoderm). Increase in skin moisturization was found at the vehicle treated sites but not at the altoderm sites. There was no increase in trans-epidermal water loss at any site. Ref. Data on file. Study carried out by Cutest Systems Ltd. 214 Whitchurch Road, Heath Cardiff CF14 3ND UK.