Randomised controlled trial of short bursts of a potent topical corticosteroid versus prolonged use of a mild preparation for children with mild or moderate atopic eczema

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Abstract

Objective To determine whether a three day burst of a potent corticosteroid is more effective than a mild preparation used for seven days in children with mild or moderate atopic eczema.

Design Randomised, double blind, parallel group study of 18 weeks' duration.

Setting 13 general practices and a teaching hospital in the Nottingham area.

Participants 174 children with mild or moderate atopic eczema recruited from general practices and 33 from a hospital outpatient clinic.

Interventions 0.1% betamethasone valerate applied for three days followed by the base ointment for four days versus 1% hydrocortisone applied for seven days.

Main outcome measures Primary outcomes were total number of scratch-free days and number of relapses. Secondary outcomes were median duration of relapses, number of undisturbed nights, disease severity (six area, six sign atopic dermatitis severity scale), scores on two quality of life measures (children's life quality index and dermatitis family impact questionnaire), and number of patients in whom treatment failed in each arm.

Results No differences were found between the two groups. This was consistent for all outcomes. The median number of scratch-free days was 118.0 for the mild group and 117.5 for the potent group (difference 0.5, 95% confidence interval −2.0 to 4.0, P = 0.53). The median number of relapses for both groups was 1.0. Both groups showed clinically important improvements in disease severity and quality of life compared with baseline.

Conclusion A short burst of a potent topical corticosteroid is just as effective as prolonged use of a milder preparation for controlling mild or moderate atopic eczema in children.

Introduction

Atopic eczema, or atopic dermatitis, is an itchy inflammatory skin disorder that affects around 15% of British school children.[1] In most children the disease follows a chronic relapsing course, and most children are managed in primary care.[1 2] Although topical corticosteroids have been the mainstay of treatment for the past 40 years, few clinical trials have studied their optimum use.[3] Side effects such as thinning of the skin can occur with these preparations. This causes anxiety for both patients and clinicians and is the main reason for patients' poor compliance with treatment.[4 5]

A recent systematic review of treatments for atopic eczema identified 83 randomised controlled trials dealing primarily with topical corticosteroids.[6] Most trials lasted less than six weeks. None were conducted in primary care, and most compared a new preparation with an established preparation, rather than addressing key issues such as duration of use, potency, and cotreatment.[7]

To achieve prolonged remission of atopic eczema many dermatologists use potent topical corticosteroids in short bursts followed by a break period with a bland emollient.[8–10] Others advocate a mild preparation, such as 1% hydrocortisone as required, to avoid local side effects such as thinning of the skin.

We aimed to determine whether a three day burst of a potent topical corticosteroid was more effective than a mild preparation used continuously for seven days, without causing an increase in thinning of the skin. We also determined the costs of these treatment regimens to the NHS.

Methods

Participants

We enrolled children aged 1 to 15 years with atopic eczema as defined by Hanifin and Rajka's modified diagnostic criteria.[11] We included patients that had had mild or moderate atopic eczema within the past month.[12] Children with severe eczema were excluded on ethical grounds. Other reasons for exclusion were known sensitivity to the study treatments or eczema confined to the face or nappy area.

We had intended to recruit children from dermatology outpatient clinics at the three teaching hospitals in the Trent region, but in order to meet recruitment targets we also enrolled children from the community. Participants were subsequently recruited from the eczema clinic at Queen's Medical Centre and

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from 13 general practices in the Nottingham area. Participants recruited from the community were identified through doctors' records on the basis of a diagnosis of eczema or the use of topical corticosteroids in the past year. We assessed children from the community at their doctors' surgery and hospital patients at the Queen's Medical Centre.

Three adults with eczema were consulted during the design phase of the study. As a result of their input we asked a local doctor to join the steering committee, subjects were referred to as participants, and the term "treatment failures" was avoided when communicating with participants. The protocol was approved by the local research ethics committee, and written informed consent was obtained for all participants.

Interventions

We performed a pragmatic, double blind, randomised controlled trial of 18 weeks' duration, with follow up every six weeks. We randomised participants to one of two treatment groups. Children in the mild arm received 1% hydrocortisone ointment twice daily for seven days. Children in the potent arm used 0.1% betamethasone valerate (Betnovate; GlaxoWellcome) twice daily for three consecutive days, followed by a base emollient only (white soft paraffin) for four days. Both treatments were dispensed in white tubes labelled A and B to maintain blinding of the treatment allocation. The contents of tube A were applied for three days then tube B for four days. In the mild arm both tubes contained hydrocortisone whereas in the potent arm tube A contained betamethasone valerate and tube B contained the base emollient. Treatment was given in seven day bursts when required.

Primary outcomes

Primary outcomes were based on reports of scratching recorded in a daily diary. Scratch scores were graded in response to "how much has your eczema made you scratch today?" from 1 (not at all) to 5 (all the time). Scores of 2 or less were categorised as a scratch-free period. Participants were assumed to be in relapse if they scored more than 2 for at least three consecutive days. The primary outcomes were the number of scratch-free days and the number of relapses during the study period. We were unable to find validated methods for capturing patient defined outcomes.[13] Nevertheless, data relating to scratch-free days from our study had good face validity when developed at a piloting stage and were acceptable to patients. In addition, results based on this scale were consistent with those obtained with the validated secondary outcome measures for disease severity and quality of life.

Secondary outcomes

Short term control was assessed by comparing the median duration of the first relapse and the median duration of the first remission in the two treatment groups. The number of undisturbed nights was also recorded in the diary. Disease severity was assessed by using the six area, six sign atopic dermatitis severity scale at intervals of six weeks.[14] Quality of life was assessed by using the children's life quality index and the dermatitis family impact questionnaire at baseline and at 18 weeks.[15 16] The proportion of treatment failures in each group was defined as the number of participants who used concurrent treatments or who were lost to follow up. Skin thickness was measured at baseline and at 18 weeks with a 20 MHz B mode ultrasound scanner (Longport International, Reading). Sites scanned were the elbow and knee creases, the lateral aspect of the forearm, and the back of the calf. An independent assessor took six measurements at fixed distances along the horizontal edge of each image, from which the mean skin thickness (epidermis and dermis) was calculated.

Sample size

To detect a difference of at least 15% in the mean number of scratch-free days between the two groups, using a two sample t test with an 0.05 two sided significance level and 90% power, we needed a sample size of 89 in each group. Allowing for attrition at 10%, we needed 100 participants in each group.

Randomisation and blinding

Randomisation was computer generated in blocks of four. The list was produced and stored by the clinical trials pharmacist at Queen's Medical Centre. Treatment packs were prepared and labelled at the pharmacy. The research assistants used consecutively numbered packs to allocate new participants to treatment groups.

Participants and assessors were blinded to group assignment during collection of the data. At the end of the study, participants, or parents for younger children, were asked to guess their treatment group to test the efficacy of blinding.

Economic evaluation

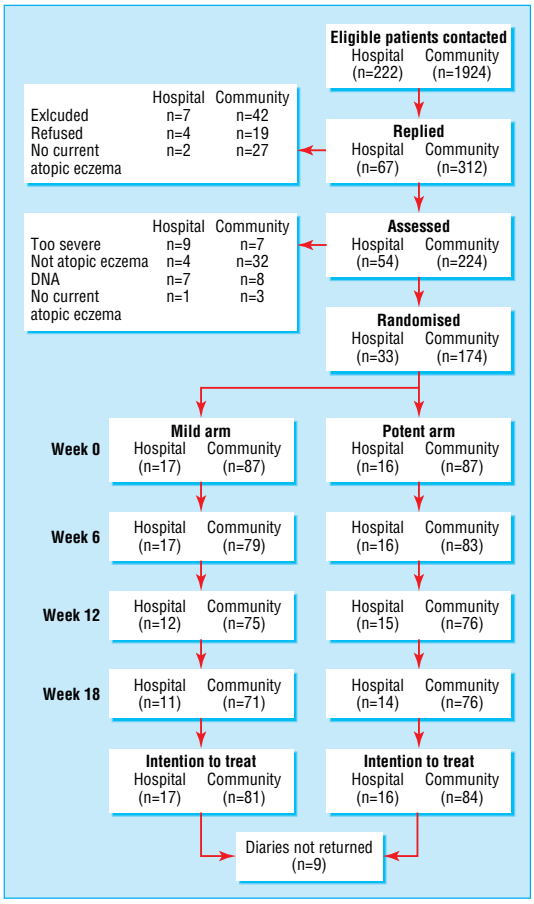
We evaluated the costs of the two treatments to the NHS. We included direct costs (ointments and rescue treatment), consultations with health professionals (with general practitioners and visits as outpatients and inpatients), and the use of prescribed drugs or treatments during the trial. We calculated the quantity of ointments used by weighing the returned tubes. Rescue treatment was deemed to be required if participants dropped out of the study because their eczema was uncontrolled. For these participants standard care was assumed on the basis of answers to questionnaires. Standard care consisted of Eumovate (GlaxoWellcome) used twice daily for three days, at a cost of 18p.

Costs of prescribed drugs were taken from the September 2000 edition of the *British National Formulary* (see table 4). The other costs came from the Personal Social Services Research Unit for the same year.[17]

Statistical methods

We analysed the data before the randomisation code was broken. Data from the diaries were highly skewed and remained so despite transformation. These data were analysed with the non-parametric Mann-Whitney U test and 95% confidence intervals produced for the median values with the CIA package 2.0.0 (Trevor Bryant, University of Southampton). All other analysis was performed in SPSS version 9.

We analysed severity scores by using a repeated measures analysis of variance. The proportions of participants achieving $>20\%$ improvement in scores at 18 weeks and of those in whom treatment failed were compared by using χ^2 tests with continuity correction. We compared changes in quality of life between the



Flow of participants through trial

groups by using Student's *t* test. Clinically important thinning of the skin was defined as >25% reduction in skin thickness compared with baseline at any of the predefined sites.

Most of the children (84%) were recruited from the community. As these participants were more likely to reflect patients treated in primary care, we concentrated our analysis mainly on them. We lodged this decision with the Cochrane Skin Group and with the NHS Executive (Trent) before analysis. Assessments of the primary outcome both included and excluded participants recruited from hospital in accordance with the original protocol.

We conducted our analysis on an intention to treat basis, and we imputed missing data by carrying forward the last known value. For the economic data if an activity was not recorded it was assumed that it had not occurred, and we recorded a zero cost.

Results

We recruited participants from October 1999 to October 2000 and completed follow up assessments by March 2001 (figure). Table 1 lists the baseline characteristics. Major differences in severity were observed between community and hospital patients at baseline: 60% and 36%, respectively, had mild disease. Community patients also had less severe eczema, less impairment of quality of life, and were less likely to use potent topical steroids, oral antibiotics, and wet wraps than hospital patients.

Primary outcomes

The median number of scratch-free days was 118.0 for the mild group and 117.5 for the potent group (difference 0.5, 95% confidence interval −2.0 to 4.0; P=0.53). Owing to a possible ceiling effect we re-examined the data, with scratch-free scored as 1 rather than 1 or 2. This resulted in fewer days reported as scratch-free (mild group, 73 (58%); potent group, 85 (67%)), although this did not alter significance (difference 12 (−16 to 9) days; P=0.7).

The number of relapses per patient ranged from 0 to 9. None were reported for 73 (44%) participants (mild arm, 36; potent arm, 37). If missing values were imputed as scratch-free days, the sensitivity analysis did not alter the findings significantly (P=0.32 and P=0.51 for scratch-free days and number of relapses, respectively).

Secondary outcomes

No differences were observed for any of the secondary outcomes between the groups (table 2). Repeated measures analysis of the severity scores showed no major differences between the groups. Both groups improved by 2.0-2.5 points compared with baseline values of 8 or 9. Improvements were achieved by six weeks and maintained throughout the study. Both groups had a similar proportion of participants who showed >20% improvement in severity (mild arm, 48 (55%); potent arm 49 (56%); P=1.00). The groups showed similar improvements in quality of life (table 2).

The proportion of participants who dropped out of the study or resorted to concurrent treatment was slightly higher in the mild than potent arm (31 (36%) *v* 22 (25%), respectively) (11% difference, −3 to 25; P=0.19). In the mild arm, six participants dropped out owing to uncontrolled eczema, 10 dropped out for other reasons, and 15 used concurrent treatments but remained in the study. In the potent arm, three participants dropped out owing to uncontrolled eczema, eight dropped out for other reasons, and 11 used concurrent treatments but remained in the study.

Adverse events

Eighteen participants reported adverse events: nine in the mild group and five in the potent group reported worse symptoms, and two in the potent group reported spots or rashes and one reported hair growth. One patient in the potent group was admitted to hospital with viral encephalitis. None of the patients developed any clinical evidence of skin thinning. Complete ultrasound data were available for 106 (51%) patients. Data were unavailable from 1 April to 31 July 2000 either because the machine was unavailable or because facilities prevented its use. The mean change in skin thickness was measured in millimetres at each site. Skin thickness of the elbow crease at baseline was 0.91 mm (mean change −0.04 (SD 0.11) mm) for the mild group and 0.99 (−0.05 (0.14) mm) for the potent group). Findings were similar at sites on the knee, calf, and forearm. Eleven participants had a reduction in skin thickness >25% at 12 sites (table 3). Four (8%) had been allocated to the mild group and 7 (12%) to the potent group (P=0.7).

Success of blinding

Of those participants who returned the final questionnaire, 39 (26%) guessed their group allocation

Table 1 Baseline characteristics of children recruited from hospital and the community with mild to moderate atopic eczema. Values are numbers (percentages) unless stated otherwise

	Hospital patients		Community patients	
	Mild arm (n=17)	Potent arm (n=16)	Mild arm (n=87)	Potent arm (n=87)
Male	8 (47)	10 (63)	49 (56)	36 (41)
White	14 (82)	15 (94)	77 (89)	79 (91)
Mean (SD) age	5 (3.2)	6 (3.0)	5 (3.8)	6 (4.0)
Family income:				
<£7999	2 (12)	2 (13)	10 (12)	8 (9)
>£34 000	3 (18)	4 (25)	16 (18)	17 (20)
Education of main care giver (basic)	9 (53)	5 (31)	35 (40)	34 (39)
Mild eczema	6 (35)	6 (38)	62 (71)	52 (60)
Mean (SD) disease severity*	13.6 (8.7)	16.2 (9.7)	8.2 (6.1)	9.0 (6.3)
Mean (SD) quality of life:				
Children's life quality index	7.6 (6.8)	7.8 (5.9)	5.1 (4.1)	5.6 (4.6)
Dermatitis family impact questionnaire	4.9 (6.1)	4.1 (5.3)	2.5 (3.2)	2.9 (3.9)
Mean (SD) skin thickness (mm):				
Elbow (n=141)	0.91 (0.2)	0.99 (0.3)	0.91 (0.2)	0.92 (0.1)
Forearm (n=142)	0.95 (0.2)	0.89 (0.1)	0.95 (0.2)	0.95 (0.1)
Knee (n=127)	1.01 (0.3)	0.98 (0.15)	0.99 (0.2)	1.04 (0.2)
Calf (n=123)	1.08 (0.2)	1.19 (0.2)	1.12 (0.1)	1.16 (0.2)
Mean (SD) areas of involved skin	8.0 (8.1)	7.6 (5.3)	2.5 (2.9)	2.8 (3.2)
Mean (SD) amount of steroid used in past month	15.7 (14.3)	12.8 (15.5)	13.8 (18.5)	14.9 (21.3)
Potent steroids prescribed	14 (88)	14 (88)	19 (23)	23 (27)
Wet wraps used	7 (41)	10 (63)	3 (3)	12 (4)
Antibiotics taken for skin in past year	7 (41)	8 (50)	20 (23)	20 (2)
Oral steroids used	3 (17)	2 (13)	3 (3)	9 (10)
Steroid inhaler used	6 (35)	8 (50)	23 (26)	29 (33)

*According to six area, six sign atopic dermatitis severity scale.

correctly, 39 (26%) guessed incorrectly, and 74 (48%) could not guess.

Economic evaluation

Participants in the mild arm used an average of 68 g of hydrocortisone and those in the potent arm used 33 g of betamethasone valerate (table 4). Both groups used similar quantities of emollients (mean 400 g). Total costs were similar for the two groups. The slightly higher mean costs for the mild group reflected the participant admitted to hospital (mean £12.11 *v* £8.61 for the mild and potent groups, respectively). This difference was not significant (mean difference £3.51, −£4.79 to £11.80; P=0.41). We present the results both with and without this participant (table 4). We restricted the evaluation to the minimisation of costs as it would be meaningless to calculate cost effectiveness ratios when there is no difference in effects or costs.

We conducted two sensitivity analyses; the first included only those participants for whom complete data were available (n=119). This increased the mean difference between groups to £7.91 but did not reach significance. The second analysis explored the cost of treating the nine participants whose eczema was not controlled by the study ointments. A sensitivity analysis that assumed treatment consisted of a consultation with a doctor plus a 30 g tube of Eumovate made little difference to either total costs or to the difference in costs between the two groups (mean difference £4.18).

Discussion

Short bursts of a potent topical steroid is just as effective as prolonged use of a mild preparation for treating atopic eczema. This was so for all primary and

Table 2 Intention to treat analysis of outcome measures of children with mild to moderate atopic eczema treated with short bursts of a potent topical corticosteroid (potent arm) or continuous use of a mild preparation (mild arm). Secondary outcomes presented for participants recruited in community only. Values are medians (interquartile ranges) unless stated otherwise

Outcome measure	Mild arm	Potent arm	Difference (95% CI)	P value
Primary outcomes				
No of scratch-free days:				
All participants (n=198)	118.0 (99.8-124.0)	117.5 (99.3-125.0)	0.5 (–3.0 to 2.0)	0.68
Community only (n=165)	118.0 (105.5-124.5)	117.5 (92.3-124.8)	0.5 (–2.0 to 4.0)	0.53
No of relapses:				
Community only (n=165)	1.0 (0.0-3.0)	1.0 (0.0-3.0)	0	0.66
Secondary outcomes				
Duration of first relapse (n=92)*	4.0 (3.0-7.5)	4.0 (3.0-9.0)	0.0 (–1.0 to 0.0)	0.33
Duration of first remission (n=89)†	6.0 (4.0-20.5)	7.0 (3.0-15.0)	–1.0 (–2.0 to 3.0)	0.95
Undisturbed nights (n=165)	123.0 (109.5-126)	121.0 (101.3-126)	2.0 (0.0 to 2.0)	0.53
Mean (SD) change from baseline:				
Children's life quality index (n=168)	–2.4 (4.0)	–1.9 (3.0)	–0.5 (–1.52 to 0.62)	0.41
Dermatitis family impact questionnaire (n=169)	–0.5 (2.4)	–0.6 (2.2)	–0.1 (–0.60 to 0.80)	0.78

*Participants who had relapse.
†Participants who had relapse followed by remission.

secondary outcomes in our study, regardless of whether community patients or community and hospital patients were analysed. Symptoms could be controlled in the community with simple cheap treatments used at an adequate dosage. Economic evaluation also showed that both treatments had similar resource implications.

Impact on skin thinning

Interpretation of the ultrasound data was difficult as methodological problems exist when this technology is used within a pragmatic randomised controlled trial. Location of the scan, time of day, temperature, and humidity affect skin thickness.[18 19] Eczematous skin is also abnormally thick (lichenified) and much of the reduction in thickness may be due to a return to normal levels. We found that eight of the 12 sites with large reductions in skin thickness had active eczema at baseline, and in all but two instances baseline skin thickness was 20%-50% higher than the mean for the site. The skin thickness after 18 weeks was within the normal range at baseline for all the participants. Therefore both mild and potent steroids seem to be safe when used appropriately over four months.

Patients' choice of treatment

Following feedback on the results, 50% of the participants who responded to the questionnaire said they would choose 1% hydrocortisone; largely because they preferred to use a mild steroid if it controlled the eczema successfully. By contrast, 50% chose to use betamethasone in short bursts as it reduced treatment time and controlled the eczema quickly. The final choice of treatment could be left to patients.

Possible explanations

The lack of difference between the mild and potent groups can be explained in several ways. Firstly, partici-

Table 3 Skin thickness measurements of children treated with short bursts of a potent topical corticosteroid or continuous use of a mild preparation showing >25% reduction in skin thickness from baseline

	Skin thickness	
	At baseline	At 18 weeks
Elbow crease:		
Potent	1.49	0.97
Potent	1.19	0.81
Potent	1.15	0.79
Potent	0.91*	0.66
Knee crease:		
Potent	1.25	0.85
Potent	1.30	0.94
Mild	1.27	0.94
Mild	1.28	0.95
Mild	1.18	0.88
Mid-point of forearm:		
Mild	1.86	1.36
Back of calf:		
Potent	1.35	0.99
Potent	0.95*	0.70

*Normal skin thickness at baseline.
Mean (SD, range) values for sites: elbow crease, 0.92 (0.2, 0.54-1.49); knee crease, 1.02 (0.2, 0.63-1.50); mid-point of forearm, 0.95 (0.1, 0.65-1.86); back of calf, 1.15 (0.2, 0.69-1.60).

Table 4 Costs of treating 87 children with mild or moderate atopic eczema in each treatment arm with topical corticosteroids for 18 weeks

		Mild arm		Potent arm	
	Unit cost	Units	£	Units	£
Direct costs					
Study ointments:		5918.5g	118.37	2857.4g	131.44
Hydrocortisone	£0.60/30 g				
Betnovate	£1.40/30 g				
Rescue treatment	@ 18p/episode 3 days Eumovate (GlaxoWellcome) twice daily	6 episodes	1.08	3 episodes	0.54
Total cost			119.45		131.98
Mean (SD) per patient			1.37 (1.4)		1.52 (1.2)
Concurrent eczema treatment					
Emollients	£6.60/500 g (Diprobase; Schering-Plough)	35 525 g	468.93	34 668 g	457.62
Topical steroids	Individually costed	29 days	6.80	44 days	2.82
Wet wraps	75p/m	0 courses	0	5 courses	3.75
Oral antibiotics	£3.68/course	7 courses	25.76	2 courses	7.36
Total cost			501.49		471.55
Mean (SD)			5.76 (8.1)		5.42 (7.9)
Consultations					
Doctor	£18.00/consultation	8	144.00	7	126.00
Phone call to doctor	£21.00/call	1	21.00	1	21.00
Outpatient	£53/consultation	0	0	0	0
Inpatient stay	£203/night	1	203.00	0	0
Casualty	£65/visit	1	65.00	0	0
Total cost			433.00		147.00
Mean (SD)			4.98 (33.3)		1.69 (6.7)
Mean (SD)†			1.50 (7.5)		1.69 (6.7)
Total cost					
Direct costs, concurrent treatment costs, and consultation costs			1,053.94	8.63 (12.9)	749.03
Mean (SD)			12.11 (37.0)	8.61 (12.8)	
Mean (SD)†			8.39 (12.9)	8.61 (12.8)	
Mean difference (95% CI); P value					3.49 (–4.81 to 11.78); 0.41)

*Student's *t* test.
†Mean (SD) excluding child admitted to hospital.

pants were mainly from the community, where disease severity was skewed towards the mild end. Secondly, entry into the study and regular contact with the researcher may have influenced parental concordance with treatment, resulting in 1% hydrocortisone, which patients often use for only one or two days, being applied for seven days.

Care has to be taken when generalising our findings to clinical practice. Prescribing the preparations without full instructions may not result in the clinical improvement we achieved.[10] Practice nurses or nurses specialised in dermatology can help promote appropriate use.[20] Greater care has to be taken when generalising our findings to secondary care, where children with severe disease predominate.

Comparison with other studies

No study to date has compared the intermittent use of mild and potent steroids for mild and moderate atopic eczema in a pragmatic way. The only published randomised controlled trial to have considered intermittent topical treatment was a 16 week study of 54 adults with moderate to severe atopic eczema.[21] Once the participants were in remission they were given either a potent topical steroid or a vehicle for two days a week for known "healed" lesions. Those in the active group had a lower risk of relapse than those in the vehicle group. Two other studies, published as abstracts, have evaluated time to relapse and intermittent treatment.[22 23]

Strengths and weaknesses of our study

The strengths of our study include its pragmatic design, long duration, and the use of patient specific outcomes alongside validated scales for severity and quality of life. The study population also reflects a wider group of patients with eczema than in previous hospital based studies and is thus better able to inform general practice, where most cases are treated. Nevertheless, some reservations exist. In particular, the median number of scratch-free days was high in both groups, which could make a further 15% reduction in symptoms difficult to achieve. Our definition of relapse may have failed to capture the true morbidity. Comparison of the number of 7 day treatment blocks initiated in each group showed that participants resorted to treatment in the absence of self reported itch (median 7 treatment blocks initiated in mild group, 8 in potent group). This contrasts with a median of one relapse defined by the scratch scores in both groups.

Recommendations for research

The liberal use of an emollient might achieve similar control to topical steroids for children with mild or moderate eczema. Researchers should consider a treatment arm of emollient only for trials based in primary care. Relapses could also be defined on the basis of parents starting treatment rather than as reported itch.

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Contributors: Jackie Thomas (research nurse) helped with data collection and management of the trial. KST was responsible for the design, the acquisition, analysis, and interpretation of the data, and drafting and revising the manuscript; she will act as guarantor for the paper. SA, AA, ALWP, CO'N, SY, and HCW were responsible for the design, the analysis and interpretation of the data, and revising the manuscript.

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Competing interests: MW has received funds from the NHS health technology assessment programme. It is possible that the NHS could gain from this research. ALWP is a consultant to Medical Solutions, a company that markets benzoyl peroxide formulations and anti-eczema products.

What is already known on this topic

Topical corticosteroids have been used to control atopic eczema for 40 years

No studies have compared short bursts of a potent preparation with prolonged use of a weak preparation for controlling mild or moderate disease

What this study adds

A short burst of a potent topical steroid is as effective and safe as prolonged use of a weak preparation for mild or moderate atopic eczema

The type of preparation is immaterial provided that the dosage is adequate

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