Eczema in children: new study finds no evidence of benefit from emollient bath additives

A UK-based randomised controlled trial involving 482 children with eczema found that emollient bath additives provided minimal or no additional benefit when added to standard eczema care. While the person’s choice of emollient bath additive product is important, the cost of treatment and the risk of adverse events, for example, slipping in the bath, should also be taken into account. The NICE guideline on eczema in under 12s recommends that emollients form the basis of the treatment of eczema and leave-on emollients should be prescribed in large quantities (250-500g per week) to enable this.

Overview and current advice

Eczema is a common, chronic condition that can have a significant negative impact on a child’s quality of life. The NICE guideline on eczema in under 12s recommends emollients as the main treatment for all severities of eczema, with other treatments, including topical corticosteroids and topical calcineurin inhibitors, used to manage active flares of eczema. The guideline recommends that children should be offered a choice of unperfumed emollients for everyday moisturising, washing and bathing.

There are 2 main types of emollients:
- emollients that are applied directly to the skin. These include creams, ointments, lotions and sprays. These products can also be used as soap substitutes, since soaps and other detergent-based wash products can dry and irritate the skin.
- emollients that are added to bath water. These are called emollient bath additives, and often come as bath oils. The person soaks in the bath for at least 10 minutes, which is intended to leave a protective film of oil over the skin.

Evidence supporting the use of emollient bath additives is lacking. A 2007 Drug and Therapeutics Bulletin article found no randomised controlled trials that evaluated the efficacy of emollient bath additives, and concluded that treatment strategies that do not use bath additives would be acceptable. Despite this, emollient bath additives are still widely prescribed, costing more than £23 million in England. In addition to this there may be risks to using emollient bath additives; the SPCs for many of these products advise patients to take care to avoid slipping in the bath.

New evidence

A UK-based, open-label, pragmatic randomised controlled trial (RCT, Santer et al. 2018) compared emollient bath additives plus standard care with standard care alone in children receiving standard eczema care.
The study included 482 children aged 1 to 11 years (mean age 5.3 years; 51% female) with atopic eczema. Children with inactive or very mild eczema (defined as a score of 5 or less on the Nottingham eczema severity scale) and children who bathed less than once a week were excluded from the study. Children were recruited from 96 GP surgeries in Wales, western England and southern England.

Children in the intervention group were prescribed emollient bath additives and asked to use them regularly for 12 months, while children in the control group were not prescribed bath additives and were asked not to use any bath additives for 12 months. The authors state that it is not possible to make a convincing placebo emollient bath additive, so an open-label study design was used. Although a specific emollient bath additive was not used in the study, the investigators encouraged practices to prescribe 1 of the 3 most widely prescribed bath products in the UK. These were Oilatum bath additive (used by 45% of the intervention group), Aveeno bath oil (used by 26%) and Balneum bath oil (used by 4.5%), with 30% of children prescribed another brand of emollient bath additive. Emollient bath additives containing antimicrobials were not permitted in the study as they may cause irritation. Both groups received written information on how to wash, including the use of leave-on emollients as a soap substitute.

The primary outcome was eczema severity, measured by parent/carer reported Patient Oriented Eczema Measure (POEM) score over 16 weeks. The POEM score is a 7-part, validated questionnaire scored from 0 to 28, with a higher score signifying more severe eczema. The minimal clinically important difference (MCID) for the POEM score is 3 points. The study was adequately powered for the primary outcome. Across both groups, the mean POEM score at baseline was 9.8 (standard deviation [SD] 5.8) points, indicating moderate eczema.

In the emollient bath additive group, the mean POEM score over 16 weeks treatment was 7.5 points (SD 6.0) from a baseline score of 9.5; in the control group the mean POEM score was 8.4 points (SD 6.0) from a baseline score of 10.1. There was no statistically significant difference in POEM score between the 2 groups over 16 weeks. After adjustment for baseline severity, confounders (including topical corticosteroid and soap substitute use), and allowing for clustering within practices and responses within participants over time, the POEM score in the no bath additive group was 0.41 points (95% confidence interval [CI] −0.27 to 1.10) higher compared with the bath additive group. This between group difference falls well below the MCID of 3 points.

No significant differences were observed between groups for any of the secondary outcomes, including POEM score at 52 weeks, quality of life (measured using the child health utility-9D), eczema exacerbation rates and quantity of topical corticosteroid used.

Adverse events were similar across groups. Over the first 16 weeks, 35% of children in each group reported at least 1 adverse event, with no significant difference between groups (odds ratio 1.4, 95% confidence interval 0.79 to 2.47). Adverse events reported across both treatment groups included slipping in bath (21%), redness (18%), refusal to bathe (10%) and stinging (2%).

The study did have some limitations that should be considered. The open-label design of the study may have introduced bias, as the parents knew which group their child was randomised to. This knowledge may have affected how they managed their child’s eczema, for example the volume of soap substitute emollient used. All participants in the study received information on the use of emollients as soap substitutes, which may have improved the skin in both groups. It is not known how emollient bath additives compare with standard care without additional information. The majority of children in the study (87%) had mild or moderate eczema at baseline. In children with more severe eczema further studies are required to determine the effectiveness of emollient bath additives.
Commentary

Commentary provided by NICE
The NICE guideline on eczema in under 12s recommends emollients for all severities of eczema, to be used every day for moisturising, washing and bathing. The guideline recommends that leave-on emollients should be prescribed in large qualities (between 250 grams and 500 grams each week), and used over the whole body, even when the eczema is clear. Parents or carers should be advised to use emollients as a substitute to soap when washing their child, and children and their parent or carers should be taught how to apply emollients; smoothing them into the skin rather than rubbing.

Emollient bath additives are widely used in clinical practice, despite a lack of good quality evidence for their benefit. A recent, large, UK-based RCT sought to address this gap, and found little to no benefit for emollient bath additives in children with atopic eczema. This research is another factor to consider, alongside other factors such as the risk of falls and the child’s preferences, when making the decision with each child and their parents or carers about which emollients to use.

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References

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