Topical analgesia with EMLA cream for curettage of molluscum contagiosum in children

Study dates: First subject enrolled: February 1986
Last subject last visit: September 1986

Phase of development: Therapeutic confirmatory (III)

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This study was performed in compliance with Good Clinical Practice, including the archiving of essential documents.

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Clinical Study Report Synopsis
Drug Substance EMLA 5% cream
Study Code 85-EM24
Edition Number 1
Date 13 September 2011

Study centre(s)
This study was conducted in 2 centres in Sweden.

Publications

Objectives and criteria for evaluation
Table S1 presents the objectives and outcome variables for this study.

Table S1 Objectives and outcome variables

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Outcome variables</th>
<th>Type</th>
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</thead>
<tbody>
<tr>
<td>To evaluate the analgesic efficacy of EMLA 5% cream when used as a topical local anaesthetic before curettage of molluscum contagiosum in children</td>
<td>Evaluation of pain verbally by the child and physician on a 4-point scale: no pain, slight pain, moderate pain, or severe pain Evaluation of pain by the child using a 100-mm horizontal VAS: 0 mm indicated “no pain” and 100 mm “severe pain”.</td>
<td>Efficacy</td>
</tr>
<tr>
<td>To evaluate any adverse reactions to EMLA 5% cream when used as a topical local anaesthetic before curettage of molluscum contagiosum in children</td>
<td>Presence of local reactions such as pallor, redness, and oedema rated as slight, moderate or severe.</td>
<td>Safety</td>
</tr>
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</table>

EMLA Eutectic mixture of local anaesthetics; VAS Visual analogue scale.

Study design
This was an open-label study to evaluate the analgesic efficacy and safety of EMLA (eutectic mixture of local anaesthetics) 5% cream used before curettage of molluscum contagiosum in children. In this study, the molluscs were covered with EMLA 5% cream and an occlusive dressing (Tegaderm™) 1 hour before curettage. A dose of 1 g EMLA 5% cream was used to cover a skin area of approximately 2.5 × 2.5 cm. Each area contained one or several molluscs. With larger skin areas, the maximum dose per subject did not exceed 10 g EMLA 5% cream. Within 5 minutes prior to curettage, the anaesthetic cream was wiped off and local dermal reactions at each application site were assessed by the physician. The skin was disinfected with isotonic 0.1% chlorhexidine acetate in water, and the molluscs were removed with a closed chalazion curet. The overall pain from the procedure was evaluated by the child and the physician.

Target subject population and sample size
Children, 3 to 14 years of age, scheduled for curettage of at least 5 molluscs, and without known or suspected allergy to amide local anaesthetics, were included in the trial. A total of 60 subjects were planned for this study.
Investigational product and comparator(s): dosage, mode of administration and batch numbers

Commercially available EMLA 5% cream was used in this study. This formulation consisted of lidocaine (25 mg [107 mmol/L]); prilocaine (25 mg [113 mmol/L]); Arlatone® 289 (19 mg); Carbopol® 934 (10 mg); and distilled water (up to 1 g [1 mL]). The total concentration of the active ingredients (lidocaine and prilocaine) was 50 mg/mL; Arlatone (emulsifier) and Carbopol (thickener) were used to obtain a suitable consistency. The investigational product was administered topically in a layer (1 g) over the selected area. (Batch number 215-020/1-05).

Duration of treatment

Subjects received a single 1-hour application of investigational product.

Statistical methods

Comparisons of the incidence of local reactions in subjects with and without atopic dermatitis were performed with Fisher’s exact test (2-tailed).

Subject population

Fifty-six children at 2 centres (14 males and 42 females, 3 to 14 years of age, with weights ranging from 15 to 46 kg) were enrolled in the trial. One female subject was withdrawn prior to treatment due to an insufficient number of molluscs resulting in 55 evaluable subjects. The subjects’ molluscs were located on the skin over all body area. Of the 55 evaluable subjects, 20 had a history of atopic dermatitis. No child received any concomitant medication.

Summary of efficacy results

Ninety-three percent of the subjects rated their pain as either none or slight, and 7% as either moderate or severe. The corresponding values for the physician assessments were 96% and 4%, respectively. Fifty-one children were able to understand the instructions and use the VAS scale; for these subjects, the median VAS score was 3 mm.

Summary of safety results

In total, 397 separate treatment areas were evaluated for the presence of local reactions. In at least 1 location where the cream was applied, local pallor (62%), redness (27%), or oedema (13%) were observed. There was no difference in the incidence between subjects with and without atopic dermatitis (p>0.05). Similarly, local redness of the skin which had been in contact with the plastic dressing (Tegaderm) was observed in 20% of the subjects. In 3 subjects with atopic dermatitis, petechiae occurred in the groin or axilla (one of these subjects also experienced itching); other treated skin areas were not affected.

Adverse events (as reported by the subject’s parents) included redness and oedema in 1 subject that was resolved at follow-up (3 weeks post treatment). Two months after the initial treatment, the subject underwent a challenge test during which EMLA 5% cream was applied without occlusion on 2 locations. The treatment areas were examined every 5 minutes.
for 1 hour; slight pallor was the only reaction observed. In another subject, postinflammatory hyperpigmentation occurred on the treated skin areas. The corresponding areas had moderate to severe erythema after removal of the cream. The pigmentation was no longer present 2 months after treatment.

**Conclusion(s)**

EMLA 5% cream (1 gm administered 1 hour prior to curettage) provided effective local anaesthesia for the curettage of molluscs in children. Local reactions observed were mild, reversible, and caused little to no discomfort. These results suggest that EMLA 5% cream could be a safe and useful alternative to general anaesthesia for most children with extensive molluscs.