EMLA cream for the removal of molluscum contagiosum on patients with atopic dermatitis

Study dates: Not available from original CSR, which predates ICH-E3 guidance

Phase of development: Therapeutic confirmatory (III)

Principal Investigator: Lena Rönnerfält, MD
Hudkliniken
Karolinska sjukhuset
Box 60500
104 01 Stockholm
Sweden

Sponsor’s Responsible Medical Officer: Bruce Minor, PhD
Astra Pain Control AB
S-15185 Södertälje
Sweden

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

This submission /document contains trade secrets and confidential commercial information, disclosure of which is prohibited without providing advance notice to AstraZeneca and opportunity to object.
Study centre(s)

This open clinical trial was conducted in 1 centre 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>
</tr>
</thead>
<tbody>
<tr>
<td>To determine if EMLA 5% cream was useful as a topical anaesthetic for surgical removal of molluscum with a 30-minute application time</td>
<td>Evaluation of pain by the subject according to a verbal rating scale: no pain, slight pain, moderate pain, or severe pain. Evaluation of pain by the physician based on subject’s reaction according to a verbal rating scale: no pain, slight pain, moderate pain, or severe pain.</td>
<td>Efficacy</td>
</tr>
<tr>
<td>To determine if there were any differences with respect to local reactions in children with atopic dermatitis.</td>
<td>Local reactions (including the presence of pallor, redness, or oedema) as evaluated by visible inspection by the physician. The severity of local reactions was weighted as follows: none = 0, slight = 1, moderate = 2 and severe = 3.</td>
<td>Safety</td>
</tr>
</tbody>
</table>

EMLA  Eutectic mixture of local anaesthetics.

Study design

This study was an open trial to determine if EMLA (eutectic mixture of local anaesthetics) 5% cream was useful as a topical analgesic for surgical removal of molluscum contagiosum in children with a history of atopic dermatitis. EMLA 5% cream was applied, together with Tegaderm®, Micropore®, or Gladpack® to form an occlusive dressing, over the molluscs 30 minutes prior to the surgical procedure. Each application of EMLA was approximately 1 g covering a skin area of approximately 2.5×2.5 cm; maximum dose was not to exceed 10 g ie, 10 treatment areas. Each treated area had 1 or more molluscs, and included skin where eczema was present and skin where eczema was not present. Immediately prior to the surgical treatment, the occlusive dressing was removed, and the skin was wiped dry and examined by the physician for any adverse reactions. The skin was then disinfected with 70% alcohol and the molluscs were removed by a closed chalazion curette. The degree of pain was assessed.
Clinical Study Report Synopsis
Drug Substance EMLA 5% cream
Study Code 86-EM14
Edition Number 1
Date 13 September 2011

first by the subject and then by the physician immediately after completion of the surgical treatment.

**Target subject population and sample size**

Male and female children, 4 to 9 years of age, with a history of atopic dermatitis and scheduled for surgical removal of at least 5 molluscs were included in the study. Children with known or suspected allergy to local anaesthetics of the amide type were excluded. A sample size of 30 subjects was planned.

**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. Tegaderm (3M), Micropore (3M), or Gladpack was used to form an occlusive dressing. The investigational product was applied topically (approximately 1 gm over an area of 2.5 × 2.5 cm. (Batch number 215 028/2-05).

**Duration of treatment**

Subjects received a single 30-minute application of investigational product prior to surgical treatment.

**Statistical methods**

Subjects with both eczematous and non-eczematous mollusc areas were included in the statistical analysis of adverse reactions. The mean severity (weighted as none=0, slight=1, moderate=2, and severe=3) of oedema, redness, and paleness was calculated for the different types of areas for each subject. The difference of the mean severity between eczematous and non-eczematous areas was evaluated by the Wilcoxon signed rank test.

**Subject population**

A total of 29 subjects were treated and analyzed. Subjects had a mean age of 5.6 (standard deviation 1.4) years and a mean weight of 21.4 kg (range, 17 to 27 kg) for males (n=9) and 21.3 kg (range, 16 to 30 kg) for females (n=20). No subjects received concomitant medication; no premedication was used prior to the surgical procedures.

**Summary of efficacy results**

In the evaluation of pain as assessed by the subject, 83% of the subjects rated the pain from the surgical procedure as either none or slight (13 and 11 subjects, respectively). The physicians rated the pain as being none or slight in 86% of the subjects (18 and 7 subjects, respectively). Moderate pain was reported by 4 subjects as assessed by both subject and
physician; severe pain was reported by 1 subject as assessed by the subject. None of the surgical procedures had to be interrupted or stopped because of pain.

**Summary of safety results**

Twenty subjects had both eczematous and non-eczematous mollusc areas which were treated with EMLA cream. There was no statistical difference with regard to redness, paleness, or oedema when areas having eczema were compared with areas not having eczema. A total of 259 separate treatment areas were evaluated for local reactions.

One subject had a severe paleness in an area where there was no eczema. In areas where eczema was present, 3 subjects had slight oedema, 1 subject had 2 areas with severe redness, and 1 subject had 1 area with severe paleness.

**Conclusion(s)**

EMLA 5% cream, at a dose of 1 g per 6.25 cm² and application time of 30 minutes provided effective local analgesia for curettage of molluscs. There was no statistical difference between redness, paleness, or oedema on areas of skin where eczema was present compared with areas of skin where eczema was not present after application of EMLA cream.