VENEPUNCTURE PAIN CAN BE REDUCED

INVESTIGATOR
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STUDY CENTRE(S)
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OBJECTIVES
Evaluate the pain relieving effect of EMLA Cream in oriental infants and possible adverse reactions.

STUDY DESIGN
This was a double-blind, randomized study.

TARGET SUBJECT POPULATION AND SAMPLE SIZE
56 oriental infants referred to the hospital for surgery.

INVESTIGATIONAL PRODUCT AND COMPARATOR(S): DOSAGE, MODE OF ADMINISTRATION AND BATCH NUMBERS
A thick layer of EMLA Cream or placebo cream (approx 2.5 g) was applied to the skin over a suitable vein (eg, dorsum of the hand, lower arm, cubital fossa), under occlusive dressing.

DURATION OF TREATMENT
EMLA or placebo was applied for 60-90 min.

VARIABLES
- Pain reactions observed by an investigator classified on a 3-graded scale: no, slight or severe pain.
Adverse reactions (eg, oedema, redness and paleness) were assessed on a 4-graded scale: no, slight, moderate and severe.

**Statistical methods**

The Mann-Whitney test was used for statistical evaluation of differences in effect between the placebo and the EMLA group.

**Subject population**

27 infants and children were included in the EMLA group and 28 in the placebo group. The median (range) age was 24 (1 - 48) months and 30 (4 – 48) months in the EMLA and placebo groups, respectively. The number of patients below 12 months of age are shown in the Table. There were no statistical differences between the groups regarding sex, age or weight.

<table>
<thead>
<tr>
<th>Age group</th>
<th>Treatment with EMLA Cream</th>
<th>Treatment with placebo cream</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &lt; 1 months</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Age 1-2 months</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Age 3-11 months</td>
<td>3</td>
<td>5</td>
</tr>
</tbody>
</table>

**Summary of results**

Treatment with EMLA resulted in significantly lower pain scores than treatment with placebo ($z = 3.74$, $p < 0.001$). There were no local skin reactions or any other adverse events observed.

**Conclusions**

EMLA significantly reduced pain during venepuncture in oriental infants. The use of EMLA may possibly have a beneficial psychological effect on children regarding their attitude towards future venepunctures..

**Study Code**

83-P013

**CSR Date**

1 August 1984