In patients with actinic keratoses (AK), is a topically applied imiquimod 5% cream more effective than placebo for clearing lesions?

**METHODS**

- **Design:** 2 concurrent randomized controlled trials subsequently merged into 1 trial for data analysis purposes.
- **Allocation:** concealed.*
- **Blinding:** blinded (patients, healthcare providers, data collectors, outcome assessors, data analysis, and the sponsor).*
- **Follow up period:** 16 weeks of treatment followed by an 8 week observational period.
- **Setting:** 24 centres in the US and Canada.
- **Patients:** 436 otherwise healthy people ≥18 years of age (mean age 66 y, 87% men) who had 4–8 clinically diagnosed AK lesions within a contiguous 25 cm² treatment area on the face or balding scalp but not both. Exclusion criteria included previous treatment with imiquimod 5% cream in the treatment area, and allergies to any excipients in the cream.
- **Intervention:** topical imiquimod 5% cream (n = 215) or placebo (n = 221) applied once per day, 2 days per week, for 16 weeks. The placebo was similar in appearance, and of identical composition to imiquimod 5% cream with the exception of the active ingredient.
- **Outcomes:** complete clearance of AK lesions in the treatment area and adverse effects assessed at weeks 1, 2, 4, 6, 8, 10, 12, 16 (end of treatment), 20, and 24 (end of post-treatment).
- **Patient follow up:** 95% (analysis was by intention to treat).*

*See glossary.

**MAIN RESULTS**

At 8 weeks post-treatment, more patients in the imiquimod group than in the placebo group achieved complete clearance of AK lesions (table). More patients in the imiquimod group than in the placebo group had itching, burning, and bleeding at the target site (table).

**CONCLUSION**

In patients with actinic keratoses, a topically applied imiquimod 5% cream was more effective than placebo for clearing lesions.

**A topical imiquimod 5% cream v placebo in actinic keratoses (AK) at 8 weeks post-treatment**

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Imiquimod (% response)</th>
<th>Placebo (% response)</th>
<th>RBI (95% CI)</th>
<th>NNT (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete clearance of AK lesions</td>
<td>45.1%</td>
<td>3.2%</td>
<td>1324% (595 to 2864)</td>
<td>3 (2 to 3)</td>
</tr>
<tr>
<td>Itching at target site</td>
<td>20.5%</td>
<td>6.8%</td>
<td>202% (75 to 424)</td>
<td>8 (5 to 14)</td>
</tr>
<tr>
<td>Burning at target site</td>
<td>5.6%</td>
<td>1.8%</td>
<td>208% (7 to 397)</td>
<td>27 (13 to 379)</td>
</tr>
<tr>
<td>Bleeding at target site</td>
<td>3.3%</td>
<td>0.5%</td>
<td>620% (170 to 4365)</td>
<td>36 (17 to 274)</td>
</tr>
</tbody>
</table>

*Abbreviations defined in glossary; RBI, RRI, NNT, NNH, and CI calculated from data in article.