Plain language summary of a clinical study (Study ID: LP0105-1032)

Potential treatment for actinic keratosis
Comparing effect of active drug with dummy drug

What is this summary about?
This summary is written to inform the public in plain language about the results of a clinical study.

A clinical study is research done on people. Such research is designed to answer questions about diseases, treatments, or other factors that can affect our health.

The results of a clinical study are described in a detailed report for researchers, health care professionals, and authorities who approve medicines. This is a short summary of that report.

Do not just look at this summary
The results shown here are from a single study. Many studies are needed to find out if a medicine works and is safe to use.

Do not change your current medical treatment based on the results shown in this summary.
Always consult your doctor.
If you would like to find more detailed information about this clinical study, please look at the table at the end of this summary.

IN SHORT

Why was this study done?
To test a treatment for people with actinic keratosis on large areas of the skin.

What was tested?
The study treatment – a gel medicine used on sun damaged skin – was compared with a dummy gel.

Who took part?
729 adult men and women with actinic keratosis were treated.

What did the study show?
Most of the participants who had the study gel had improvement in their actinic keratosis.
Few of the participants who had the dummy gel had improvement in their actinic keratosis.
The study gel had side effects. The most common side effects were pain and itch in the area where the study treatment had been put on the skin.

1. When and where was this study done?
The study started in April 2015 and ended in February 2017. It took place in 3 countries: United States, Canada, and Australia.

2. What disease was studied?
The participants in this study had actinic keratosis – a common disease that affects 11 to 25 out of 100 adults. Actinic keratosis is a disease in the skin, and it shows up as thickened and scaly lesions. It normally develops on areas of the skin that are often out in the sun, for example face, ears, scalp, neck, forearms, and the back of the hands.

If the disease is not treated it may develop into a form of skin cancer called squamous cell carcinoma.

Right now, there are treatments available for those actinic keratosis lesions which are visible. Better medicines for treatment of large areas of the skin are needed.

3. Why was this study done?
Researchers wanted to test if a known gel treatment for actinic keratosis worked better than dummy gel when used in large treatment areas.

4. Who took part in this study?
Altogether 729 people took part in the study: 535 men and 194 women between 38 and 91 years old. The participants had between 5 and
20 actinic keratoses in the area of the skin where the treatment gel was applied.

There were no European countries involved with this study.
- United States: 402 participants
- Canada: 247 participants
- Australia: 80 participants

5. What treatments were studied?
Two gel treatments were compared:
- Ingenol mebutate gel, called ‘study gel’ in this summary
- a dummy gel

A dummy gel looks and feels like the study gel but does not have any medical ingredients. New treatments are often compared with a dummy treatment in clinical studies.

The study gel was compared with the dummy gel to check:
- if the study gel helped improve the actinic keratosis
- if the study gel improved the actinic keratosis more than the dummy gel did
- if the study gel had more side effects than the dummy gel

6. How was the study done?
2 out of 3 participants were treated on the skin with the study gel, and the rest were treated with the dummy gel. It was decided by chance which treatment each participant received.

Neither the participants nor the study doctor knew which treatment the participants received.

Each study participant was treated 3 days in a row with either study gel or dummy gel. After the treatment, the study doctors looked at the participants’ skin to see whether the actinic keratoses had improved. This was done twice - 8 weeks after the treatment and again after 12 months. The study doctors also looked for side effects of the treatment.

7. What did the study show?
The actinic keratosis improved for more of the participants who were treated with the study gel than it did for those who were treated with the dummy gel.

No visible actinic keratoses on the treated skin 8 weeks after treatment

This was the main result of the study. More results are included in a detailed report for researchers. The table at the end of this summary shows where to find this report.

8. What were the side effects?
The graph and text below show the side effects that the study doctors believed were caused by the treatments.

405 of the 549 participants (73.8%) who received study gel had side effects.
16 of the 176 participants (9.1%) who received dummy gel had side effects.

Side effects during the first 8 weeks

There were 8 participants who received study gel and 2 participants who received dummy gel with side effects that were rated as serious. However, none of these side effects were thought to be caused by the study gel or the dummy gel.

1 participant died after the first 8 weeks of a heart attack, but the death was not thought to be caused by the study gel.

Most common side effects
The majority of participants (70.9%) had side effects that were reactions in the skin that had
been treated with study gel. The most common side effects were:

- A burning sensation in the area where the study treatment had been used
- Itchy skin and pain in the area where the study treatment had been used

After the first 8 weeks, the participants were followed for another 12 months. In this period, more participants who were treated with study gel had side effects than those who were treated with the dummy gel. None had serious side effects.

**Side effects after the first 8 weeks**

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<th>Percentage of participants with side effects</th>
<th>Study gel</th>
<th>Dummy gel</th>
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<tr>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>20%</td>
<td>11%</td>
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<tr>
<td>100%</td>
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**Leaving the study because of side effects**

There was 1 participant (0.2%) who received study gel and left the study before the end because of side effects. This participant had a type of cancer known as a lymphoma. This lymphoma was not thought to be caused by the study gel.

**9. How will this study help patients and researchers?**

This summary only shows the results of this one study. Other studies may show different results.

This study has given information to the researchers which may be used for developing future drugs to treat actinic keratosis.

**Are there plans for further studies?**

There are no plans for other studies with the study treatment.

**Where can I find more information about the study?**

You can find more information about this study in other places, as shown in the table below. A clinical study has a unique identifier (ID) in databases and publications. Please use the relevant ID, if necessary, when you search for more information.

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**Company responsible for this study:** LEO Pharma A/S

Please email any enquiries to: disclosure@leo-pharma.com

**Study name:** Efficacy and Safety of Ingenol Mebutate Gel in Field Treatment of Actinic Keratosis on Full Face, Balding Scalp or Approximately 250 cm² on the Chest
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