Comparing two medicines for psoriasis:
a foam medicine and a gel medicine

What is this summary all 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 compare 2 medicines used on the skin of people with psoriasis – a skin disease
• To find out which of the 2 medicines worked best at improving the psoriasis

What was tested?
• A foam medicine was compared with a gel medicine
• The foam and the gel had the same medical ingredients

Who took part?
• 463 adult men and women with mild, moderate, or severe psoriasis

What did the study show?
• More people who used the foam medicine had improvement in their psoriasis compared with the people who used the gel medicine
• Very few participants in this study had side effects

1. When and where was this study done?
The study started in June 2014 and ended in March 2015. It took place in 3 countries:
• France (11 clinics)
• UK (15 clinics)
• USA (15 clinics)

2. What disease was studied?
The participants in this study had psoriasis – a common skin disease that affects around 2 out of 100 people.

The study participants had a type of psoriasis called plaque psoriasis. Plaques are thick, flaky patches of skin. Plaques are often found on the knees, elbows and back, but they may be found on all parts of the body. Since the disease may be both painful and visible, people living with psoriasis often have a reduced quality of life. Right now, there is no cure for psoriasis. But there are several treatments that can make the signs and symptoms of the disease better.

3. Why was this study done?
Researchers wanted to compare 2 medicines used to treat skin with psoriasis, to see which medicine worked best. One medicine was a foam and the other was a gel. Both medicines had the same medical ingredients.

This study was a so-called 'phase 3' study. In a phase 3 study, the medicine has already been tested in many earlier studies in animals and...
people. The main goal of a phase 3 study is to confirm in a larger group of patients that the medicine works and is safe.

4. Who took part in this study?
In total, 463 men and women with psoriasis took part in the study.

- **168 women**
- **295 men**

Participants could join the study only if they:
- were at least 18 years old
- had mild, moderate, or severe psoriasis on their body, legs, or arms

Most participants had moderate psoriasis when they joined the study.

- **295 of the participants were from an EU country** (France or the UK), and **168 were from the USA**:
  - France: 122 participants
  - UK: 173 participants
  - USA: 168 participants

5. What medicines were studied?
Altogether, 4 medicines were studied – **2 real and 2 dummy medicines**.

A dummy medicine looks and feels like the real medicine but does not have any medical ingredients. Real medicines are often compared with dummy medicines in clinical studies.

**The 2 real medicines were:**
- a foam medicine called **LEO 90100 aerosol foam**
- a gel medicine called **Calcipotriol BDP gel**

The foam and gel medicines both had the same amount of 2 medical ingredients:
- calcipotriol: a vitamin D-like molecule
- betamethasone dipropionate: a steroid hormone

**The 2 dummy medicines were:**
- a dummy foam medicine
- a dummy gel medicine

The dummy medicines were compared with the real medicines to check:
- if the foam and the gel without any medical ingredients helped improve the psoriasis
- if the real medicines caused any more side effects than the dummy medicines

6. How was the study done?
Each study participant received only 1 of the 4 medicines studied. It was decided by chance which medicine each participant received.

The study doctor did not know which medicine the participants received. The participants knew if they had received foam or gel, but they did not know if it was the real medicine or the dummy medicine.

The study participants used the medicine on the psoriasis plaques on their skin once every day for 12 weeks. They visited their clinic every week or every 2 weeks. At each visit, the study doctor looked at their skin to see if their psoriasis had improved. The study doctor also looked for any side effects of the medicine.

The gel medicine was expected to take longer than the foam medicine to improve the psoriasis. Therefore, the researchers compared the participants’ level of psoriasis after:
- **4 weeks of treatment with the foam**
- **8 weeks of treatment with the gel**
7. What did the study show?

More participants using the foam medicine achieved ‘clear’ or ‘almost clear’ skin compared with those who used the gel medicine.

![Graph showing percentage of participants with clear or almost clear skin after treatment with foam or gel medicine.]

- **Foam**: 38% (71 of 185)
- **Gel**: 22% (42 of 188)

8. What were the side effects?

The graph and text below sum up the side effects that the study doctors believed were caused by the medicines. Other reports of this study may also include side effects that the doctors believed were not caused by the medicines – but by other factors.

27 of the 463 participants (6%) in this study had side effects. Some participants had more than 1 side effect or had the same side effect more than once. Altogether, the 27 participants had 37 cases of side effects.

A few more participants using the foam or dummy foam medicine had side effects compared with the participants who used the gel or dummy gel medicine.

![Graph showing percentage of participants with side effects in each treatment group.]

- **Foam**: 8% (14 of 185)
- **Dummy foam**: 8% (4 of 47)
- **Gel**: 4% (7 of 188)
- **Dummy gel**: 5% (2 of 43)

### Serious side effects

1 participant had a side effect that was rated as serious because the participant had to go to hospital. This was a result of the participant’s psoriasis getting worse, after 10 weeks of treatment with the foam medicine.

### Most common side effects

The most common side effects were:

- local itch, where the medicine was used on the skin
- general itch
- worsening of psoriasis

Fewer than 5% of the participants in each treatment group (foam, dummy foam, gel, and dummy gel) had these side effects.

### Leaving the study because of side effects

3 participants left the study before the end because of their side effects:

- 1 participant who used the foam medicine left the study early because of local itch
- 1 participant who used the gel medicine and 1 participant who used the dummy foam left the study early because their psoriasis got worse

9. How has this study helped patients and researchers?

This study was part of a research programme with many studies. Researchers need to look at the results of many studies to find out how well the foam medicine works in people with psoriasis, and how safe it is. This takes a lot of people in many countries all around the world.

This summary only shows the results of this 1 study. Other studies may show different results.

### Are there plans for further studies?

The foam medicine is being studied for long-term use (1 year) in a study called LP0053-1004.
10. 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: LEO 90100 aerosol foam compared to calcipotriol plus betamethasone dipropionate gel in subjects with psoriasis vulgaris