

LAY SUMMARY (Plain Language Summary) — Dermalexiin Study

Clinical Trial Results Summary for the Public

Title of Study:

Testing a New Cream (Dermalexiin 5%) to Treat Moderate-to-Severe Atopic Dermatitis (Eczema) in adults

Sponsor:

MolendiiP Pharma Ltd

1. Why was this study done?

Atopic dermatitis (also known as eczema) is a chronic inflammatory skin condition that causes redness, itchiness, irritation, and damage to the skin barrier.

It can seriously affect a person's quality of life, leading to sleep problems, emotional distress, and social difficulties. However, several treatments are available, including creams, tablets, and injections, but not all patients respond well.

Some treatments can also cause unwanted side effects or are unsuitable for long-term use.

This study was designed to test a new topical treatment called Dermalexiin (DLX-412).

Researchers wanted to find out whether Dermalexiin could safely and effectively reduce the symptoms of moderate-to-severe eczema without causing serious side effects.

2. Who took part in the study?

This study included 100 adults between 18 and 65 who had been diagnosed with moderate-to-severe atopic dermatitis (eczema).

Participants were recruited from four specialist dermatology centres across the United Kingdom.

There was an approximately equal number of men and women in the study.

All participants gave written informed consent to participate in the research before any study procedures began.

3. What treatments were studied?

Participants were randomly assigned to one of two groups:

- One group received Dermalexiin 5% cream, which they applied once daily to the affected areas of their skin.
- The other group received a placebo cream. This cream looked, smelled, and felt the same as Dermalexiin but contained no active medicine.

Participants were asked to apply their assigned cream every day for 12 weeks.

After the treatment ended, all participants were monitored for another 4 weeks to check for any delayed side effects or changes in their condition.

4. What happened during the study?

Before the study began, the study doctors assessed all participants to ensure they met the eligibility criteria.

These checks included a review of their medical history and an examination of their skin condition.

Once enrolled, participants were instructed to apply their assigned cream (Dermalexiin or placebo) once daily to the affected areas.

Participants attended regular clinic visits during the 12-week treatment period, during which time doctors monitored their skin symptoms, levels of itchiness, and overall quality of life. In addition to measuring how well the treatment worked, doctors also checked for any side effects or other health changes.

Participants were followed for an additional 4 weeks after treatment ended to ensure their ongoing safety.

5. What were the main results?

Participants who used Dermalexiin 5% cream improved their eczema symptoms more than those who used the placebo cream.

After 12 weeks of treatment:

- Dermalexiin users had an average 65% improvement in their Eczema Area and Severity Index (EASI) scores.
- Placebo users had an average 35% improvement.

Participants treated with Dermalexiin also reported a greater reduction in itchiness and better scores on quality-of-life measures.

The differences between the Dermalexiin and placebo groups were statistically significant, meaning they were unlikely to have occurred by chance.

6. What side effects were seen?

About 20% of participants using Dermalexiin 5% cream and 18% of participants using the placebo cream reported mild side effects.

Both groups' most common side effects were mild redness (erythema) and itching (pruritus) at the site where the cream was applied.

These side effects were usually mild and went away without stopping the treatment.

No serious side effects related to the study treatments were reported in either group.

There were no deaths, and no unexpected safety problems occurred during the study.

Doctors continued to monitor participants for 4 weeks after the treatment ended, and no new side effects were identified during the follow-up period.

7. What do the results mean?

The results of this study suggest that Dermalexiin 5% cream may help improve the symptoms of moderate-to-severe atopic dermatitis in adults while being well tolerated.

Participants using Dermalexiin showed better skin symptoms, itchiness, and quality of life than those using a placebo.

Although these findings are promising, further studies involving larger groups of patients and longer treatment periods are needed to confirm Dermalexiin's effectiveness and safety.

8. Who sponsored the study?

This study was sponsored by MolendiiP Pharma Ltd, a company that develops new treatments for skin conditions and other medical needs.

Disclaimer

This Lay Summary was developed for educational and demonstration purposes only.

Dermalexiin (DLX-412), MolendiiP Pharma Ltd, and the described clinical trial (DERM-001) are fictional constructs.

No real clinical study was conducted.