

The effect of therapeutic treatments in the transplant model of psoriasis; in which a psoriatic lesion is induced in non-lesional skin transplanted onto immune-deficient (BNX) mice by injecting super-antigen activated peripheral blood cells intra-dermally into the transplant.

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The main objective of the study is to see if the test compounds can prevent the development of a psoriatic lesion induced in non-lesional skin from psoriasis patients which has been transplanted onto immune-deficient mice.

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|------------------------------|------------------------|
| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Autoimmune disorders |
| Study type | Observational invasive |

Summary

ID

NL-OMON42470

Source

ToetsingOnline

Brief title

The effect of therapeutic treatments in the transplant model of psoriasis

Condition

- Autoimmune disorders
- Epidermal and dermal conditions

Synonym

psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Galderma

Source(s) of monetary or material Support: Industry

Intervention

Keyword: biopsies, psoriasis, skin, transplants

Outcome measures

Primary outcome

Transplant epidermal thickness.

Secondary outcome

Number of dividing epidermal keratinocytes.

Study description

Background summary

Psoriasis is an auto-immune skin disease in which pro-inflammatory protein mediators, released by skin cells and infiltrating cells, cause an abnormal cell division and differentiation. It may be possible to treat psoriasis using drugs aimed at preventing the synthesis of such mediators. The mouse transplant model of psoriasis is a suitable one in which to test new compounds.

Study objective

The main objective of the study is to see if the test compounds can prevent the development of a psoriatic lesion induced in non-lesional skin from psoriasis patients which has been transplanted onto immune-deficient mice.

Study design

Small (6 mm diameter) biopsies will be removed from non-lesional skin of volunteers with psoriasis and transplanted onto immune-deficient mice. A psoriasis lesion will be induced in the transplant by injecting it

intra-dermally with the patient's white blood cells. A week later we will begin treating mice with the test and control chemicals. After 3 weeks the transplants will be harvested.

Study burden and risks

The health risks associated with this research are small, possibly slight scar formation or discoloration of skin at the biopsy sites.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients with psoriasis vulgaris, mild to moderate.

Exclusion criteria

Volunteers should not:

- use light therapy or systemic drugs such as methotrexate or cyclosporine A.
- use local topical corticosteroids.
- develop psoriasis at wound sites (Köbner phenomenon).
- have other skin diseases.
- be pregnant

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 07-01-2016

Enrollment: 19

Type: Actual

Ethics review

Approved WMO

Date: 26-10-2015

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

| Register | ID |
|----------|----------------|
| CCMO | NL54880.098.15 |