

The development and validation of models of human skin diseases for drug testing

Published: 03-06-2013

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To develop and validate transplant models of vitiligo and atopic dermatitis for drug testing.

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

Summary

ID

NL-OMON38558

Source

ToetsingOnline

Brief title

disease models

Condition

- Other condition
- Skin vascular abnormalities

Synonym

atopic dermatitis, psoriasis, vitiligo

Health condition

Developing human skin disease models

Research involving

Human

Sponsors and support

Primary sponsor: Derphartox

Source(s) of monetary or material Support: Provincie Zuidholland;Derphartox

Intervention

Keyword: diseases, human, models, skin

Outcome measures

Primary outcome

N.A.

Secondary outcome

N.A.

Study description

Background summary

There is a need for models of skin diseases for testing and developing new therapies

Study objective

To develop and validate transplant models of vitiligo and atopic dermatitis for drug testing.

Study design

Volunteers will donate skin biopsies (3 x 5 mm diameter) and blood (27 ml) which will be used in a mouse transplant model.

Study burden and risks

N.A.

Contacts

Public

Derphartox

Galileiweg 8
Leiden 2333BD
NL

Scientific

Derphartox

Galileiweg 8
Leiden 2333BD
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Volunteers (male/female) are 18 years or older, suffering from psoriasis vulgaris, vitiligo or atopic dermatitis.

Exclusion criteria

Volunteers cannot be taking immune-modulating drugs.

Volunteers cannot have UV/light therapy.

If donating lesional skin biopsies then patients cannot use topical treatments up to 2 weeks before donating the biopsies (they can use placebo creams to treat dry skin).

Volunteers should not have problems with the Köbner phenomenon.

Volunteers should not 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): 01-10-2013

Enrollment: 36

Type: Actual

Ethics review

Approved WMO

Date: 03-06-2013

Application type: First submission

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

metc-ldd@lumc.nl

Approved WMO

Date: 07-08-2014

Application type: Amendment

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 | NL42861.098.13 |