

Single center ethical protocol for donation of skin tissue and blood samples by patients suffering from psoriasis vulgaris for animal study 20879/02 concerning development of new treatments for psoriasis vulgaris.

Published: 29-08-2016

Last updated: 15-04-2024

Collection of skin tissue and blood samples from patients with mild to moderate psoriasis for efficacy testing of a new compound in a humanized mouse model, and validation of the mouse model.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45443

Source

ToetsingOnline

Brief title

Donation of skin tissue and blood for research in animal study 20879/02

Condition

- Other condition
- Epidermal and dermal conditions

Synonym

Psoriasis research in laboratory animals

Health condition

Donatie weefsel voor proefdieronderzoek voor psoriasis (gehumaniseerd muismodel)

Research involving

Human

Sponsors and support

Primary sponsor: Triskelion B.V.

Source(s) of monetary or material Support: Triskelion B.V.;in opdracht van Grunenthal GmbH

Intervention

Keyword: Humanized mouse model, Psoriasis Vulgaris, Skin biopsy

Outcome measures

Primary outcome

Not applicable

Secondary outcome

Not applicable

Study description

Background summary

Psoriasis is a highly prevalent disease (2-3% worldwide) with great impact on the quality of life of patients. Current treatments are suboptimal. The development of novel therapeutics requires validation in a preclinical animal model. Since the skin of most laboratory animals differs significantly from humans, a humanized mouse model for psoriasis can be applied to evaluate the efficacy of compounds to treat psoriasis vulgaris.

Study objective

Collection of skin tissue and blood samples from patients with mild to moderate psoriasis for efficacy testing of a new compound in a humanized mouse model, and validation of the mouse model.

Study design

Single-center study in the Netherlands

Intervention

Collection of 48 mL blood and 5 skin biopsies

Study burden and risks

- Blood samples will be collected via vena-puncture with possible risks of slight hemorrhages and bruising at the puncture site. Furthermore, the subject may faint or experience dizziness.

- Skin tissue will be collected via a skin biopsy procedure (under local anaesthesia) with the possible risks of mild pain, bleeding from the biopsy site, local reaction to the anesthetic and scar tissue formation. The risks are considered to be very low.

There is no direct benefit for the subjects participating in the study as the skin and blood samples will be collected for further use in animal studies, investigating new treatments for psoriasis vulgaris.

Contacts

Public

Triskelion B.V.

Utrechtseweg 48
Zeist 3704 HE
NL

Scientific

Triskelion B.V.

Utrechtseweg 48
Zeist 3704 HE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Written informed consent obtained
- Suffering of mild to moderate psoriasis vulgaris
- PASI score of 18 or less and minimum body surface area of 3% at visit 1

Exclusion criteria

- Suffering from extensive psoriasis or having had a non-plaque or drug-induced form of psoriasis.
- A recent serious infection or a history of chronic or recurrent infectious disease.
- Undergoing light therapy or any systemic therapy in the last year

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 27-03-2017

Enrollment: 50

Type:

Actual

Ethics review

Approved WMO

Date: 29-08-2016

Application type: First submission

Review commission: METC Brabant (Tilburg)

Approved WMO

Date: 05-04-2017

Application type: Amendment

Review commission: METC Brabant (Tilburg)

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

CCMO

ID

NL58662.028.16