

Single center ethical protocol for donation of skin tissue and blood samples by patients suffering from psoriasis vulgaris for animal studies concerning development of new treatments for psoriasis vulgaris

Published: 21-10-2014

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Collection of skin tissue and blood samples from patients with mild to moderate psoriasis for further research in a humanized mouse model.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40921

Source

ToetsingOnline

Brief title

Donation of skin tissue and blood samples for research in animal studies

Condition

- Other condition

Synonym

Psoriasis research in laboratory animal study

Health condition

Donatie weefsel voor proefdieronderzoek (gehumaniseerd muismodel) voor psoriasis

Research involving

Human

Sponsors and support

Primary sponsor: TNO Triskelion

Source(s) of monetary or material Support: TNO Triskelion

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 an animal model. Since the skin of most test 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 further research in a humanized mouse model.

Study design

Single-center study in the Netherlands

Intervention

Collection of blood samples (40 mL)

Collection of skin tissue (4 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 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

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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 a minimum of BSA of 3% at Visit 1

Exclusion criteria

- Suffering from extensive psoriasis or having had nonplaque or drug-induced forms of psoriasis
- Undergoing light therapy or any systemic therapy
- A recent serious infection or a history of chronic or recurrent infectious disease

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 15-10-2014

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

Date: 21-10-2014

Application type: First submission

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	ID
CCMO	NL50948.028.14