Validation of the humanized psoriasis model in NIHIII mice with compounds from the clinic

Published: 23-04-2014
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In this study the material of 20 donors is used to validate the humanized mouse model for psoriasis with clinically relevant compounds.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Observational invasive

Summary

ID

NL-OMON40678

Source
ToetsingOnline

Brief title
Validation of the humanized psoriasis model

Condition

- Epidermal and dermal conditions

Synonym
Flaking disease, Psoriasis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Drug testing, Efficacy, Humanized Mouse Model, Psoriasis

Outcome measures

Primary outcome

After finalization of the validation study, the transplanted biopsies are isolated to study the psoriatic process via histological techniques. The primary read-out is epidermal thickness.

Secondary outcome

After finalization of the validation study, the transplanted biopsies are isolated to study the psoriatic process via histological techniques. The secundary read-out is proliferation and differentiation of cells in the skin.
Also, serum is collected on day 21, in which e.g. cytokine measurements can be performed to evaluate the systemic immune reaction.
Moreover, the activation and differentiation status of immune cells will be determined in the blood of the donors.

Study description

Background summary

Psoriasis is a highly prevalent disease (2-3% world wide) with great impact on the quality of life of patients. Current treatments are suboptimal. The development of new compounds requires validation in an animal model. However, the skin of most animals vs humans differs significantly.
TNO Triskelion has developed a humanized model for psoriasis in mice. In this model, non-laesional skin from psoriasis patients is transplanted onto a mouse. After engraftment, the psoriatic process is synchronized via injection of autologous immune cells. Since the study concerns pre-clinical testing of novel drug candidates, patients will not experience direct (therapeutic) benefit from

participation.

Study objective

In this study the material of 20 donors is used to validate the humanized mouse model for psoriasis with clinically relevant compounds.

Study design

TNO Triskelion aims to validate the humanized mouse model for psoriasis with clinically relevant compounds. Subsequently, the model can be applied to analyse the efficacy of novel therapeutics for psoriasis. Besides ethical permission for the use of laboratory animals, also medical ethical clearance is required for isolation of skin biopsies and blood from psoriasis patients. The skin will be transplanted onto mice after which autologous immune cells (isolated from the blood of the patients) will be injected into the graft to synchronize the psoriatic process. As indicated in the study protocol (Appendix 1), 4 skin punch biopsies of non-laesional skin as well as blood will be obtained from each individual patient.

Study burden and risks

TNO Triskelion has signed with an insurance company for the sporiasis patients that participate in this study (see appendix 5). Nevertheless, medical risks are minimal. A week after isolation of skin and blood samples, the stitches will be removed at the research center (PT&R) and a final check will take place. With the consent of the patient, the medical practitioner of each patient will be notified about the participation.

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

Adult Psoriasis patients, m/f, with a mild to moderate form of psoriasis vulgaris, i.e. a maximal PASI score of 18 and a minimum BSA of 3%. Patients are allowed to use local corticosteroids or ointments to prevent dry skin (see Appendix 2).

Exclusion criteria

Psoriasis patients have NOT received light therapy or another form of SYSTEMIC treatment (e.g. treatment with methotrexate, cyclosporin A or anti-TNF). Gender or age of the adult patients are no exclusion criteria (see Appendix 2).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	19-05-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	23-04-2014
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	NL49057.028.14