Characterization and extending the use of the humanized mouse model for psoriasis for pre-clinical testing of new drug.

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Characterization and extending the use of the humanized mouse model for psoriasis for pre-clinical testing of new drug.Limited screening of compound B for a pharmaceutical company.Therefore, depending on the success rate of transplantation and…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON34915

Source
ToetsingOnline

Brief title
Expanding knowledge on psoriatic process in the humanized mouse model

Condition

- Autoimmune disorders
- Epidermal and dermal conditions

Synonym
flaking disease, psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: Interne TNO gelden

Intervention

Keyword: characterize, humanized, mouse, Psoriasis

Outcome measures

Primary outcome

Effect on the psoriatic process is tested by histology and immuno-histochemical

techniques in the transplanted biopsies. Main read-out epidermal thickness.

Secondary outcome

Additionally, several markers which are know to be associated with lesional

psoriasis skin wil be evaluated. This allows us to make a better comparison

between the human situation and the processes seen in the model.

Study description

Background summary

Psoriasis is a highly prevalent disease which has great impact on the quality
of life of patients. Current treatments are far
from ideal. The development of new compounds requires validation in a animal
model, however many differences exsist
between the skin of most animals and humans.
The department of biosciences at TNO has acquired expertise in the past year in
transplanting human psoriasis skin on to
a mouse. Thereby, we are able to do pre-clinical testing of compounds for
psoriasis. Non-leasional skin is transplanted
after which injection with stimulated T cells induces the psoriatic process.
Scientific background information can be read in Appendix 3 &1 because this
study involves pre-clinical testing, patients will
not experience a direct benifit from participation.

Study objective

Characterization and extending the use of the humanized mouse model for psoriasis for pre-clinical testing of new drug.

Limited screening of compound B for a pharmaceutical company.
Therefore, depending on the success rate of transplantation and injection, some of the question stated below will be answered in later studies.

Study design

In this experiment we want to:
- study the dynamics of the psoriatic process and the elements which influence this process: (needing +/- 10patients)
- determine the efficacy of other treatments used in the clinic (vitamine D analogs, cyclosporine...): +/- 10 patients
- attempt to validate a prophylactic validation with betamethasone: (needing +/- 6 patients)
- characterization of the processes in normal skin after transplantation onto mice and determine if imiquimod will induce psoriasis like pathology in this skin (as has been reported in mice) : 10 healthy controls

Study burden and risks

TNO has arranged Insurance for the patients and healthy controls participating in this study. However, medical risks are very low. A week after obtaining skin and blood samples, the stitches will be removed at the research center (PT&R) and a check will take place.
With the consent of the patient, the medical practicioner of each patient will be notified about the participation.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Psoriasis patients: Adults (m/f) with a mild form of psoriasis vulgaris (PASI score of maximal 6). Patients are allowed to use localcorticosteriods or ointments to prevent dry skin (see appendix 2).;Healthy controls: Adults (m/f) who do not have skin condition (as recognized by physisian or dermatologist)

Exclusion criteria

Psoriasis patients: These patients have not received light therapy or another form of systemic treatment (methotrexaat, cyclosporin A,anti-TNF treatments). Gender or age of the adults are not a exclusion criteria.(see appendix 2);Healthy controls: are not to undergo treatment with drugs like prednisolon and cyclosporine.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-09-2010
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO Date:	22-03-2010
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	29-04-2010
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	ID
CCMO	NL31570.028.10