Efficacy of a three novel compounds in a humanized mouse model of psoriasis

Published: 20-04-2011
Last updated: 28-04-2024

In this study effect of 3 novel compounds on the development of psoriasis in the humanized mouse model isinvestigated. The efficacy is compared to one registered drug, namely Remicade(R).

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

Summary

ID

NL-OMON35935

Source
ToetsingOnline

Brief title
Pre-clinical efficacy of 3 compounds in psoriasis

Condition

- Autoimmune disorders
- Epidermal and dermal conditions

Synonym
flaking disease, psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Pfizer
Source(s) of monetary or material Support: Farmaceutisch bedrijf

Intervention

Keyword: inflammation, mouse, psoriasis, skin

Outcome measures

Primary outcome

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

techniques in the transplanted biopsies.

Main read-out is epidermal thickness.

Secondary outcome

Serum markers in blood of transplanted mice will be studied together with

markers on cultured cells from psoriasis

patients. Possibly also inflammatory markers in the skin tissue will be

evaluated.

Study description

Background summary

Psoriasis is a highly prevalent disease with great impact on the quality of life of the patients. Current treatments are far from ideal. The development of new compounds requires validation in an animal model, however, many differences exist between the skin of most animals and humans.
TNO Earth, Environment and Life Sciences has acquired expertise in the past year in transplanting human psoriasis skin onto a mouse. Thereby, we are able to perform pre-clinical testing of compounds for psoriasis. Non-laesional skin is transplanted onto a mouse and after engraftment injection with autologous T-cells synchronizes the psoriatic process.
Scientific background information can be read in Appendix 3. Since the study involves pre-clinical testing, patients will not experience a direct benefit from participation.

Study objective

In this study effect of 3 novel compounds on the development of psoriasis in the humanized mouse model is
investigated. The efficacy is compared to one registered drug, namely Remicade(R).

Study design

A pharmaceutical company has asked TNO to test a 3 potential new therapies for psoriasis in our humanized mouse model of
psoriasis.
Besides animal welfare approval, we also need medical ethical clearance for obtaining skin biopsies and blood from
psoriasis patients.
The skin will be transplanted onto mice after which autologous T-cells (isolated from the blood of patients) will be injected
into the graft to synchronize development of psoriasis. As indicated in the study protocol (Appendix 1), 4 skin punch
biopsies will be obtained from non-lesional skin as well as 5 vials of blood (ca. 10 ml each).

Study burden and risks

TNO has arranged insurance for the patients 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.
\Mth the consent of the patient, the medical practicioner of each patient will be notified about the participation.

Contacts

Public
Pfizer

Inflammation and Immunology RU, 200 Cambridge Park Drive
Cambridge, MA 02140
GB
Scientific
Pfizer

Inflammation and Immunology RU, 200 Cambridge Park Drive
Cambridge, MA 02140
GB

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 areallowed to use local corticosteroids or ointments to prevent dry skin (see Appendix 2).

Exclusion criteria

Psoriasis patients: These patients have not received light therapy or another form of systemic treatment (methotrexate, cyclosporin A, anti-TNF treatments). Gender or age of the adults are not exclusion criteria (see Appendix 2).

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):	01-06-2011
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO 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	NL36398.028.11