The effect of CD07813 in the transplant model of psoriasis; in which a psoriatic lesion is induced in non-lesional skin transplanted onto immune-deficient (BNX) mice by injecting activated peripheral blood cells intra-dermally into the transplant. RD/10/15700

Published: 09-03-2011
Last updated: 27-04-2024

In previous projects a number of compounds were tested that had a positive effect in the transplant model of psoriasis. However, it proved difficult to prepare formulations that were stable enough to use in clinical studies. A new compound (CD07813...

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

Summary

ID

NL-OMON35876

Source
ToetsingOnline

Brief title
The effect of CD07813 in the transplant model of psoriasis

Condition

- Autoimmune disorders
- Epidermal and dermal conditions

Synonym

psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Galderma
Source(s) of monetary or material Support: industry

Intervention

Keyword: blood, Psoriasis, Skin biopsies

Outcome measures

Primary outcome

N.A

Secondary outcome

N.A

Study description

Background summary

Small (5 mm diameter) biopsies from healthy skin of psoriasis patients (volunteers) will be transplanted onto immune-deficient mice. A psoriasis lesion will be induced in the transplant by injecting the volunteers super-antigen activated white blood cells into the transplant. One week later we will start treating the transplants topically with the various test substances.

Study objective

In previous projects a number of compounds were tested that had a positive effect in the transplant model of psoriasis. However, it proved difficult to prepare formulations that were stable enough to use in clinical studies. A new compound (CD07813) has now been developed (a modification of 1of the previous chemicals) which is active in vitro and also has good pharmaceutical properties. this will be tested in the mouse psoriasis model.

Study design

Volunteers (psoriasis patients) will donate 3 x 0.5 mm skin biopsies and 27 ml blood. The skin to be removed (non-involved skin) will be disinfected and the anaesthetised by injecting it with xylocaine. Three 0.5 mm diameter skin biopsies will then be taken and the wound sites closed using stitches. The wounds will be covered with a plaster and kept dry for 24 hrs. After 7 days the stitches will be removed.

Study burden and risks

The risks associated with the research are small, possible small scars or discolouration at the biopsy site.

Contacts

Public
Galderma

Les Templiers
2400 Route des Colles, F-06410 BIOT
FR
Scientific
Galderma

Les Templiers
2400 Route des Colles, F-06410 BIOT
FR

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with mild to moderate psoriasis vulgaris

Exclusion criteria

Volunteers cannot be taking systemic drugs to treat their psoriasis, or immune-modulators for other diseases
Volunteers cannot be undergoing UV/light therapy
Volunteers should not show the Kobner phenomenon at wound sites.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-08-2011
Enrollment:	17
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL35571.098.11