

The effect of BS6.890C in the prophylactic transplant model of psoriasis in which a psoriatic lesion is induced in non-lesional skin transplanted onto immune-deficient (BNX) mice by injecting superantigen activated peripheral blood cells intra-dermally into the transplant.

Published: 12-08-2014

Last updated: 21-04-2024

The aim of the project is to test BS6.890C in the prophylactic transplant model of psoriasis.

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

Summary

ID

NL-OMON41006

Source

ToetsingOnline

Brief title

The effect of BS6.890C in the transplant model of psoriasis

Condition

- Other condition
- Autoimmune disorders

- Epidermal and dermal conditions

Synonym

Psoriasis

Health condition

testing drugs using a humanized mouse model of psoriasis

Research involving

Human

Sponsors and support

Primary sponsor: Bioprojet-Biotech

Source(s) of monetary or material Support: industry

Intervention

Keyword: psoriasis, skin, transplant

Outcome measures**Primary outcome**

Not applicable.

Secondary outcome

Not applicable.

Study description**Background summary**

5mm diameter full thickness skin biopsies from non-lesional skin from a volunteer with psoriasis, are transplanted onto immune-deficient mice. A psoriatic lesion is induced in the transplant by injecting autologous white blood cells into the transplant. Potential drugs can be tested to see if they prevent development of the psoriasis lesion.

Study objective

The aim of the project is to test BS6.890C in the prophylactic transplant

model of psoriasis.

Study design

Volunteers skin is disinfected and anaesthetised. 3 x 5mm full thickness skin biopsies are taken from each donor and the biopsy sites closed with a stitch. The wounds are then covered with a bandage. Wounds are kept dry for 24 hr and after 7 days the stiches are removed.
Blood (3 x 9ml tubes) is taken in heparinized tubes.

Study burden and risks

The health risks associated with donating the skin biopsies and blood are small, possibly a small scar and/or discoloration of skin at the biopsy site.

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

Patients with psoriasis vulgaris (light to mild)

Exclusion criteria

Volunteers can not use systemic drugs (for their psoriasis).

Volunteers cannot have UV-light therapy.

Volunteers cannot use immune-modulating drugs for other diseases.

Volunteers should not have problems with the Köbner phenomenon.

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): 06-10-2014

Enrollment: 15

Type: Actual

Ethics review

Approved WMO

Date: 12-08-2014

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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	NL49848.098.14