

The effect of GRT21750T and GRTR775 on spontaneous cytokine expression by lesional psoriasis explants in vitro.

Published: 05-02-2016

Last updated: 20-04-2024

The aim of the project is to study the effect of GRT on the synthesis and cytokine release in psoriasis lesions. This information can establish the right formulation and dose of GRT for further research.

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

Summary

ID

NL-OMON43378

Source

ToetsingOnline

Brief title

The effect of GRT on cytokine expression in psoriasis

Condition

- Epidermal and dermal conditions

Synonym

psoriasis

Research involving

Human

Sponsors and support

Primary sponsor: Grunenthal

Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: cytokine, expression, psoriasis

Outcome measures

Primary outcome

Cytokine synthesis and release after treatment with GRT.

Secondary outcome

Not applicable.

Study description

Background summary

Psoriasis is an auto-immune disease in which pro-inflammatory protein mediators, released by skin cells and infiltrating cells, cause an abnormal cell division and differentiation. It may be possible to treat psoriasis using drugs aimed at preventing the synthesis of such mediators.

Study objective

The aim of the project is to study the effect of GRT on the synthesis and cytokine release in psoriasis lesions. This information can establish the right formulation and dose of GRT for further research.

Study design

Lesional skin biopsies of 3 mm in diameter will be treated with GRT in vitro. By measuring the effect of the cytokine synthesis and release, it is possible to establish the right formulation and dose of GRT for further research.

Study burden and risks

The health risks associated with taking skin biopsies are small. It is possible to obtain a slight scar formation and/or discolouration at the site of the biopsy punch.

Contacts

Public

Grunenthal

Zieglerstraße 6

Aachen 52099

DE

Scientific

Grunenthal

Zieglerstraße 6

Aachen 52099

DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients with moderate to severe psoriasis

Exclusion criteria

Volunteers undergoing UV/light therapy or taking systemic drugs such as cyclosporin A or methotrexate

Volunteers using local topical corticosteroids

Volunteers developing psoriasis at wound sites (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): 02-03-2016

Enrollment: 5

Type: Actual

Ethics review

Approved WMO

Date: 05-02-2016

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

CCMO

ID

NL56196.098.15