Monitoring Skin Immune System (SIS) alterations in HS during treatment with biologics.

Published: 03-11-2020
Last updated: 08-04-2024

To investigate the changes in the skin immune system after 12 weeks of biologic therapy treatment in patients with HS.

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin appendage conditions
Study type	Observational invasive

Summary

ID

NL-OMON49777

Source
ToetsingOnline

Brief title
SIS alterations in HS during biologic therapy

Condition

- Skin appendage conditions

Synonym
acne inversa, Verneuil's disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: acne inversa, biologics, immunology

Outcome measures

Primary outcome

The main study parameter is the change in gene expression profile in lesional, peri-lesional an uninvolved skin in patients with HS after 12 weeks of biologic treatment.

Secondary outcome

- Microbial changes profile in lesional, peri-lesional an uninvolved skin in patients with HS after 12 weeks of biologic treatment.

- Immunohistochemical changes profile in lesional, peri-lesional an uninvolved skin in patients with HS after 12 weeks of biologic treatment.

- Change in protein expression profile in lesional, peri-lesional an uninvolved skin in patients with HS after 12 weeks of biologic treatment.

Study description

Background summary

Hidradenitis suppurativa has a complex immune driven pathogenesis involving a wide variety of immune cells, chemokines and cytokines. However, to what extent which pathways among this complex interplay of immune cells and cytokines are altered by biologic therapy is remains unclear.

Study objective

To investigate the changes in the skin immune system after 12 weeks of biologic therapy treatment in patients with HS.

Study design

Explorative and experimental study design.

Study burden and risks

A skin biopsy is a generally safe routine dermatological diagnostic procedure, however there is a small risk of bleeding and infection.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Age *18 years.
2. Indication for and starting with a biologic.
3. Able and willing to give written informed consent and to comply with the

study requirements.

Exclusion criteria

1. Use of any medication potentially affecting the skin immune system or skin microbiome.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-07-2020
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-11-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL72653.078.20