Differences in unaffected skin of patients with hidradenitis suppurativa compared with healthy controls.

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To compare the microbiome, histology, immunohistochemistry and gene expression profile of healthy skin from the axillae or groin of 10 healthy volunteers with uninvolved axilla or groin skin from age, gender, body mass index, and smoking status...

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

Summary

ID

NL-OMON49510

Source
ToetsingOnline

Brief title
Is HS healthy skin healthy?

Condition

- Autoimmune disorders
- 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, Hidradenitis Suppurativa, Histopahtologie, Immunologie, Microbiology

Outcome measures

Primary outcome

Primary outcome:

The difference in gene expression profile of unaffected skin from the axillae

or groins of HS patients and healthy controls.

Secondary outcome

Secondary outcomes:

1. Microbial differences in uninvolved skin of HS axillae or groins and that of

healthy controls.

2. Histological and immunohistochemical differences in uninvolved skin of HS

axillae or groins and that of healthy controls

Study description

Background summary

Hidradenitis suppurativa (HS), is a chronic, recurrent, auto-inflammatory skin disease located in the inverse areas of the body. The disease is characterized by the development of inflammatory nodules, sinus tracts, scars and abscesses. Multiple studies have sought to investigate the immune profile in HS comparing lesional skin with uninvolved skin. However, until recent, there was no clear definition what uninvolved skin entails, and it is unclear whether unaffected skin from an HS predilection site can be readily assumed to be similar to healthy skin. Therefore we aim to assess the microbial, histological, and molecular differences between uninvolved skin of the axillae or groins of HS patients and that of healthy controls.

Study objective

To compare the microbiome, histology, immunohistochemistry and gene expression profile of healthy skin from the axillae or groin of 10 healthy volunteers with uninvolved axilla or groin skin from age, gender, body mass index, and smoking status matched HS patients undergoing surgery and from whom excised tissue is available.

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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, HS patients must meet all of the following criteria:
- Adults (* 18 years old) suffering from HS
- Competent and willing to provide informed consent.

In order to be eligible to participate in this study, healthy controls must meet all of the following criteria:
- Adults (* 18 years old) not suffering from HS
- Competent and willing to provide informed consent.

Exclusion criteria

Exclusion criteria for HS patients:
- Use of systemic or local antibiotics in the axillae or groin in the past 2 weeks
- Use of any other medication potentially affecting the immune system or microbiome

Exclusion criteria for healthy controls:
- <18 years of age
- Presence of any inflammatory (skin) disease
- Positive family history of HS
- Use of systemic or local antibiotics in the axillae or groin in the past 2 weeks
- Use of any other medication potentially affecting the immune system

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2020
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-03-2020
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	NL72204.078.19