Hair microbiome in healthy controls relative to hidradenitis suppurativa

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

Summary

ID

NL-OMON48304

Source
ToetsingOnline

Brief title
HS-HAIR

Condition

- Other condition

Synonym
acne inversa, verneuil's disease

Health condition

De proefpersonen fungeren als de controle groep van patienten met de huidziekte, dit betreft gezonde haren vanuit huid van gezonde proefpersonen

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: hidradenitis suppurativa, microbiome

Outcome measures

Primary outcome

The main study parameter is the difference of the HS immune response, inclusive antimicrobial peptides, in relation to its microbiome compared to that of healthy individuals.

Secondary outcome

Differences in microbiome composition between healthy controls and patients with HS.

Study description

Background summary

HS is considered a complex disease involving different risk factors such as lifestyle and environmental factors, as well as genetic factors. The clinical presentation is reminiscent of bacterial infection. However, the structure of the bacterial population, as well as the diversity at the strain level, is poorly understood.

Study objective

The main objective is to collect hair samples from healthy participants, predilection and distant non-involved body sites of healthy subjects and from HS patients, for next generation sequencing and gene expression profiling, which will allow a wide range of research questions related to hair follicle steady state microbiology, immunology and pathology of HS patients relative to healthy controls.

Study design

An explorative and experimental study design.

Study burden and risks

The healthy subject will not directly benefit from this research, but participation contributes to increasing knowledge about HS and subsequently improving treatment and care.

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

1. Age * 18 years
2. Not suffering from hidradenitis suppurativa
3. Competent and willing to provide informed consent

Exclusion criteria

1. Age < 18 years
2. Use of systemic and local antibiotics in the past 2 weeks
3. Use of any other medication potentially affecting the follicular microbiome

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):	01-11-2019
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	04-10-2019
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	NL69844.078.19