THE MORPHOLOGY OF THE BASEMENT MEMBRANE ZONE OF HAIR FOLLICLES IN HIDRADENITIS SUPPURATIVA: A PILOT STUDY

Published: 11-03-2014
Last updated: 20-04-2024

To describe the composition of the BMZ along the interfollicular and follicular epidermis of perilesional HS skin and to investigate whether the expression of these proteins differs from normal skin of healthy control patients. Additionally, a...

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

Summary

ID

NL-OMON40233

Source
ToetsingOnline

Brief title
Morphology of the basal membrane zone in hidradenitis suppurativa

Condition

- Skin appendage conditions

Synonym
acne ectopica, acne inversa

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: basal membrane zone, hair follicle, hidradenitis suppurativa

Outcome measures

Primary outcome

To determine with direct immunofluorescence (DIF) whether there is a difference in expression of the BMZ components BP180, collagen type VII, laminine-332 and integrine*4 at the interfollicular epidermis and hair follicles between HS patients and healthy controls. Additionally, a PAS-staining of the skin samples will be performed to compare the degree of positivity between perilesional HS skin and normal skin from healthy controls. Finally, the morphology of the normal hair follicle localized on apocrine gland bearing skin will be described.

Secondary outcome

Not applicable.

Study description

Background summary

Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease that mainly occurs on the apocrine gland bearing skin. The pathogenesis of HS is largely unknown but several studies have shown that the initiating event takes place at the hair follicle. A recent study demonstrated a lack of PAS-staining positivity at the sebofollicular junction in perilesional skin of patients with HS. This lack of PAS-positivity might be a reflection of a structural defect in the follicular basal membrane zone (BMZ) in HS. This weakness in the BMZ could induce the release of hair follicle contents into the dermis that subsequently trigger an inflammatory reaction. We hypothesize that this weakness might be caused by a diminished presence of one or more important components of the

basal membrane zone at specific parts of the hair follicle, including BP180, laminine-332, intergrine*4 and collagenVII.

Study objective

To describe the composition of the BMZ along the interfollicular and follicular epidermis of perilesional HS skin and to investigate whether the expression of these proteins differs from normal skin of healthy control patients. Additionally, a hematoxylin and eosin (HE) staining will be performed on skin biopsies obtained from healthy volunteers to describe the normal morphoogy of the hair follicle.

Study design

Observational study.

Study burden and risks

Skin samples of HS patients will be obtained during surgery at the armpits or groins for HS as part of the medical treatment. Normally, the removed skin during this surgery is thrown away. However, when patients have given informed consent for participation in the study, biopsies will be taken from this removed skin. These biopsies will be anonymously stored until a DIF and PAS-staining is performed. No extra skin will be removed during surgery for the purpose of this study so the patient will not experience any burden from participating and there are no risks related to participation. However, participation will not be of benefit for the patient. To draw any conclusions on the results from the staining of skin biopsies of HS patients, it is necessary to compare these with stainings from healthy control skin. Skin of healthy volunteers will be obtained by means of a 4mm punch biopsy under local anaesthesia. It is a generally safe procedure with minimal burden to the patient. Possible complications of bruising, bleeding, infection and scarring rarely occur.

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 HS who have been planned for surgical treatment of HS, aged 18-50 years.;Healthy volunteers with no skin diseases located in the armpits, aged 18-50 years

Exclusion criteria

Lack of informed consent

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2014
Enrollment:	22
Type:	Actual

Ethics review

Approved WMO Date:	11-03-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-04-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL47372.042.14