Ki-67 and cytokeratin 16 expression in several lesion types of hidradenitis suppurativa compared to keratosis pilaris and psoriasis inversa. A pilot investigation

Published: 22-12-2016 Last updated: 11-04-2024

To investigate whether the upregulation of CK16 and Ki-67 (a marker for cell proliferation) in the FPSU is specific for HS, measured in inflammatory nodules and pseudo-comedones, in comparison to other dermatologic conditions that have comparable (...

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

Summary

ID

NL-OMON43302

Source ToetsingOnline

Brief title Pilot: Ki-67 and CK16 in HS, keratosis pilaris and psoriasis inversa

Condition

Skin appendage conditions

Synonym

acne ectopica, acne inversa, hidradenitis suppurativa

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: FPSU, Hidradenitis suppurativa, Keratins

Outcome measures

Primary outcome

To investigate the expression of cytokeratin 16 and ki-67 in the different

segments of the FPSU of all the above mentioned conditions

Secondary outcome

N.A.

Study description

Background summary

This study protocol concerns a follow-up investigation of the recently completed study *Expression of cytokeratins and notch in the healthy folliculopilosebaceous unit*. Currently, results about the cytokeratin expression (CKs) have been analyzed. In short, the aim of that study was to investigate the expression of various CKs in the epidermis and intact folliculopilosebaceous units (FPSU) in perilesional and lesional HS skin and to compare this to the FPSUs of healthy controls. The main finding was that CK16 expression was significantly increased in lesional HS skin compared to healthy controls at the interfollicular epidermis (IFE) and infundibulum (IFN) of the FPSU. This upregulation appears to be secondary to activation of the IFE and IFN reflected by interfollicular and infundibular hyperkeratosis in lesional skin, but not in perilesional skin. CK 1, 2e, 10, 14, 15, 17 and 25 did not show an altered expression profile. Moreover, CK expression in HFs below the IFN of HS skin was normal. In this follow-up study we further want to investigate the role of CK16 in the pathogenesis of HS.

Study objective

To investigate whether the upregulation of CK16 and Ki-67 (a marker for cell

proliferation) in the FPSU is specific for HS, measured in inflammatory nodules and pseudo-comedones, in comparison to other dermatologic conditions that have comparable (histo)pathological features such as follicular hyperkeratinisation and inflammation: keratosis pilaris and psoriasis inversa.

Study design

design: observational study

study: four months

Setting:

Department of Dermatology of the University Medical Center Groningen

Procedure:

Skin samples (four millimeter (mm) punch biopsies are taken, under a local anesthetic The biopsy will be taken in the direction of the hair in order to optimize the chances of obtaining the full PFSU in the biopsy:

1. Healthy volunteers:

the skin biopsy samples from 5 healthy volunteers will be analyzed. Locations: armpits and groin

2. Patients with keratosis pilaris:

the skin biopsies from 5 patients will be analyzed. Locations: upper arms, thighs, buttocks.

3. Patients with psoriasis inversa:

the skin biopsies from 5 patients will be analyzed. Locations: armpits and groin 4. Patients with pseudo-comedones lesions in hidradenitis suppurativa:

the skin biopsies from 5 patients will be analyzed. Locations: armpits and groin 5. Patients with inflammatory nodules in hidradenitis suppurativa:

the skin biopsies from 5 patients will be analyzed. Locations: armpits and groin

Stainings:

A hematoxylin and eosin (HE) staining is performed to evaluate the presence of the various segments of the FPSU. Only if at least the infundibulum and the interfollicular epidermis are present, the expression of the proteins cytokeratin 16 and Ki-67 can be explored.

Important note: From earlier studies we learned that the chance of obtaining these sections of the FPSU in a biopsy is about 50%. Unfortunately, there is no technique available that increases the chance of obtaining of a complete FPSU. Because we aim at examining 5 biopsies per skin condition mentioned above, we ask for permission of taking a maximum of 10 biopsies per skin condition. In other words, a maximum of 50 biopsies will be taken from 50 individuals, of which is expected that 25 will be suitable for further analysis.

Immunohistochemistry for Ki-67 is performed on the coupes which comply with the above. Thereafter, the coupes willen be stained by immunofluorescence technique for cytokeratin 16.

Scoring:

The intensity of the staining are scored by 2 independent investigators.

Study burden and risks

The burden and risks associated with participation in the control group is negligible. Punch biopsies are part of everyday practice at the Dermatology department and seldom lead to complications like wound infection. The procedure will take approximately 5 to 10 minutes and no further visits are required except for removal of the stitch (takes approximately 2 minutes).

Contacts

Public

Universitair Medisch Centrum Groningen

Hanzeplein 1 Groningen 9700RB NL **Scientific** Universitair Medisch Centrum Groningen

Hanzeplein 1 Groningen 9700RB NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years)

4 - Ki-67 and cytokeratin 16 expression in several lesion types of hidradenitis supp ... 5-05-2025

Inclusion criteria

Healthy controls:

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Subjects are not affected with HS, psoriasis inversa and keratosis pilaris.

- Subjects do not have another skin disease located at the armpits or groins

- Age 18-65 years

*

Patients with psoriasis inversa and keratosis pilaris:

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Subjects are not affected with HS

- Subjects do not have another skin disease located at the site of the affected skin.

- Age 18-65 years; Patients with HS that have pseudo-comedone lesions

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Subjects are not affected with psoriasis inversa. Also, subjects are not affected with keratosis pilaris at the site of pseudo-comedones.

- Subjects do not have another skin disease located at the site of the affected skin.

- Age 18-65 years; Patients with HS with inflammatory nodules via left-over material from STEEP-surgery

- Subjects are not affected with psoriasis inversa. Also, subjects are not affected with keratosis pilaris at the surgical site.

- subjects do not have other skin manifestations at the site of STEEP-surgery, particularly no psoriasis inversa and keratosis pilaris.

- Age 18-65 years

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Subjects who have not given informed consent

- Subjects <18 and >65 years old

Study design

Design

Observational invasive
Other
Non-randomized controlled trial
Open (masking not used)

Primary purpose: Basic science

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	03-03-2017
Enrollment:	50
Туре:	Actual

Ethics review

Approved WMO	
Date:	22-12-2016
Application type:	First submission
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 CCMO **ID** NL59868.042.16