The occurrence of pruritis in patients with hidradenitis suppurativa: a cross-sectional study

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Primary:To determine the prevalence of pruritis in patients with hidradenitis suppurativa.Secondary:- to evaluate pruritis severity and its effect on three elements of daily activities;- to evaluate differences in extensiveness of HS in relation to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Epidermal and dermal conditions
Study type	Observational invasive

Summary

ID

NL-OMON43391

Source
ToetsingOnline

Brief title
Pruritis in patients with hidradenitis suppurativa

Condition

- Epidermal and dermal conditions

Synonym
acne ectopica, acne inversa

Research involving
Human

Sponsors and support

Primary sponsor: Dermatologie EMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: hidradenitis suppurativa, pruritis

Outcome measures

Primary outcome

The 5D Pruritis Scale (5).

Numeric Rating Scale (NRS) for pruritis.

Secondary outcome

The HS severity Hurley stage (6).

The number of anatomical regions affected by HS.

Serum levels of tryptase, hemoglobin, ureum and bilirubin.

Study description

Background summary

Hidradenitis suppurativa (HS), also known as acne inversa, is a chronic, recurrent, inflammatory skin disease. The disease mostly develops after puberty and is characterized by painful, inflammatory nodules and abscesses mainly located at the axillae and groin. The disease is common, with an estimated prevalence rate between 1 and 4%. The pathogenesis of HS is still not fully understood, but infundibular hyperkeratosis, causing follicular occlusion is thought to be the primary event followed by rupture with an inflammatory response.
The key physical symptoms of HS are pain due to inflammation of the skin and purulent foul-smelling discharge in case of abscesses and fistulas. In general, pruritis is a prominent symptom of many dermatological (inflammatory) diseases, including atopic dermatitis, psoriasis, urticaria and postburn healing.
Pruritis is a multidimensional phenomenon with sensory discriminative, cognitive, evaluative and motivational components. Pruritis has many similarities to pain. Both are unpleasant sensory experiences, but the behavioral response patterns differ - pain elicits a reflex withdrawal, whereas itch leads to a scratch reflex. In addition to the other characteristics of HS, chronic or recurrent pruritus can contribute to a significant reduction in quality of life.
In psoriasis pruritis is a common symptom and a prevalence rate of 30% to 90%

is described. To date, the occurrence of pruritis in HS has not been widely examined. Since the prevalence of pruritis in HS is unknown, we will conduct a questionnaire-based survey according to a cross-sectional approach.

Hypothesis
We hypothesize a prevalence of 50-75% in patients with hidradenitis suppurativa, depending on HS disease severity and number of affected anatomical regions.

Study objective

Primary:
To determine the prevalence of pruritis in patients with hidradenitis suppurativa.

Secondary:
- to evaluate pruritis severity and its effect on three elements of daily activities;
- to evaluate differences in extensiveness of HS in relation to pruritis severity and the number of anatomical regions affected by HS.
- to screen the serum levels of pruritis markers tryptase, hemoglobin, ureum and bilirubin in a subset of patients.

Study design

Cross-sectional study.

Invasive for a subset of approximately 30 patients (Nature and extent of the burden and risks associated with participation, benefit and group relatedness).

Study burden and risks

Patients will be recruited during routine clinical care. All patients will be asked to fill out the standardized *5D Pruritis Scale* questionnaire once. HS patients with a VAS >7 for pruritis in the last 24 hours will be asked to give permission for a one-time collection of blood samples (3 tubes) by venipuncture. For this selected group of approximately 30 subjects in the HS group there are minor additional risks associated with participation as a result of the venipuncture. The very minimal risks of venipuncture include excessive bleeding, fainting or feeling light-headed, hematoma or blood accumulating under the skin, infection (a slight risk any time the skin barrier is broken) and multiple punctures to locate veins. There is no extra visit due to the study for all participants. Clinical (outcome) parameters will be collected during routine care and derived from medical charts. All personal data of the participating patients will be replaced by a code. The patient*s data will be added in a database using this code. Further research will be done

with this anonymized database. All research data will be handled in accordance with the Dutch Data Protection Act and the privacy regulations of the Erasmus MC. No data that can be traced back to the participating patients will be used in study documents, reports or in publications of this research.

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

Adult (> 18 years old) male or female patients suffering from HS at the department of Dermatology at the Erasmus MC in Rotterdam.

Exclusion criteria

Subjects with concomitant skin diseases causing pruritis, such as eczema, psoriasis will be excluded.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-03-2016
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	10-03-2016
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	NL56556.078.16