Prevalence of clinical and ultrasound enthesitis in patients with hidradenitis suppurativa

Published: 19-10-2018
Last updated: 11-04-2024

To determine the prevalence of enthesitis, both clinical and on US, in patients with HS.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON46310

Source
ToetsingOnline

Brief title
EntHS-study

Condition

- Joint disorders
- Epidermal and dermal conditions

Synonym
acne inversa, hidradenitis suppurativa

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: enhtesitis, hidradenitis suppurativa, prevalence, spondylartropathy

Outcome measures

Primary outcome

To determine the prevalence of enthesitis in HS patients using physical examination, according to the MASE, and ultrasound, according to the MASEI, as golden standard

Secondary outcome

- To determine the prevalence of clinical arthritis of patients with HS.

- To determine the prevalence of dactylitis in patients with HS.

- To determine the prevalence of inflammatory backpain in patients with HS.

- To determine the prevalence of extra-articular SpA features, like psoriasis, IBD and uveitis, in patients with HS.

- To determine the quality of life of patients with HS and SpA features.

Study description

Background summary

Hidradenitis Suppurativa (HS), also called acne inversa, is a chronic inflammatory disease of the skin. HS is associated with metabolic changes like dyslipidaemia and other chronic inflammatory diseases like inflammatory bowel disease (IBD), acne conglobata and spondyloarthritis These conditions share a dysregulation of the innate immune system, which is supported by the fact that the HS lesions are characterised by an enhanced expression of neutrophils and macrophages. Recent studies have shown that there is a high association of HS with inflammatory back pain. There was also found a high prevalence of patients with enthesitis. Enthesitis is a central feature of spondyloarthritis (SpA).
The presence of a peripheral enthesitis is used in the European Spondylarthropathy Study Group Criteria for SpA. It is hard to detect a SpA early, because of the poor specificity of symptoms of SpA. Diagnostic

investigation of a possible enthesitis with ultrasound is a highly useful and sensitive tool in the evaluation of enthesitis and improves the ability of clinical examination. Evidence of common inflammatory pathways and the fact that the prevalence of inflammatory rheumatology disorders is higher in patients with HS provides adequate support for future studies to continue investigating the relationship between SpA en HS. The aim of this study is to investigate the prevalence of a clinical enthesitis in patients with HS using clinical examination and ultrasonography as golden standard.

Study objective

To determine the prevalence of enthesitis, both clinical and on US, in patients with HS.

Study design

A mono-centre, descriptive, cross-sectional study.

Study burden and risks

The participants data will be collected during physical examination and an ultrasound. Dermographic data will be collected from the chart. These examinations are minimal invasive with a neglectable risk. The burden of the patient is restricted to one visit of the outpatient clinic with the duration of one hour.

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

18 years or older
Mentally competent
Diagnosed with HS according to the European guidelines of dermatology

Exclusion criteria

No written informed consent
Poor knowledge of the Dutch language

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-10-2018

Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	19-10-2018
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	NL67014.078.18