Metformin for Hidradenitis Suppurativa

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25659

Source
NTR

Brief title
MetForMe

Health condition

Hidradenitis Suppurativa

Sponsors and support

Primary sponsor: ZonMw
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

International Hidradenitis Suppurativa Severity Score System (IHS4)

Secondary outcome

Insulin resistance and metabolic syndrome
Clinical efficacy
patient reported outcomes as NRS-pain, DLQI, Flares, treatment satisfaction and

recommendation
Cost-effectiveness
Bio-markers
Safety and Tolerability

Study description

Background summary

A randomized controlled trial investigating the metformin is the treatment for hidradenitis suppurativa. Metformin combined with doxycycline will be compared to the standard treatment of doxycycline monotherapy for HS severity and the effect on the pre-diabetic condition.

Study objective

Metformin combined with doxycycline will result in a better improvement in HS severity and the pre-diabetic condition of the patients compared to doxycycline monotherapy.

Study design

12 and 24 weeks

Intervention

Metformin

Contacts

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Pim Aarts

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Eligibility criteria

Inclusion criteria

• Age ≥18 years at baseline
• A diagnosis of HS for at least 1 year prior to baseline
• mild to moderately active disease defined by a HS Physician Global Assessment (HS-PGA) score of 2-3 and the Refined Hurley classification of mild to moderate at baseline
• Indication for systemic therapy; i.e. uncontrolled disease under conventional topical therapy.
• Able and willing to give written informed consent and to comply with the study requirements

Exclusion criteria

• Pregnant and lactating women
• Concomitant diabetes mellitus
• Use of antibiotics within 14 days prior to baseline
• Use of immunosuppressing/modulating therapies within 28 days prior to baseline
• A known allergy to metformin or doxycycline or any of the ingredients metformin or doxycycline

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	25-01-2021

Enrollment:	62
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9050
Other	METC Erasmus MC : EMCD20022

Study results