The efficacy of laser hair removal therapy in patients with mild to moderate HS, a randomized controlled trial.

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The primary objective of this study is to assess whether laser hair removal therapy improves the course and severity of mild to moderate HS, as assessed by the difference in IHS4 between groups over time between month 7 to month 12.

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin appendage conditions
Study type	Interventional

Summary

ID

NL-OMON53989

Source
ToetsingOnline

Brief title
Laser hair removal in HS

Condition

- Skin appendage conditions

Synonym
Acne inversa, Verneuil's disease

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: Hair laser, Hidradenitis suppurativa, Treatment

Outcome measures

Primary outcome

The primary endpoint of this study is the difference in IHS4 between the intervention group and the control group over month 7 to 12, using a repeated measure analysis.

Secondary outcome

Patient reported outcome measures (for the axillae):

- Skin related pain of the axillae, on a numerical rating scale (NRS)

- Skin related itch of the axillae, on a NRS

- Self-reported flares (number of flares reported by the patients in the last 4 weeks)

- Quality of life measured with the Dermatologic Life Quality Index (DLQI) and the Hidradenitis Suppurativa Quality of Life score (HiSQOL), during the study.

- Difference in patients satisfaction score

Clinical efficacy (for the axillae):

- Difference in cumulative IHS4 over month 7 to 12 between both groups.

- Cumulative IHS4, correlated to hair loss over month 7 till 12.

- Cumulative IHS4, calculated over a time period of 3, 9 and 12 months

- Pustule and papule count during visits during the study.

- (cumulative) Abscess en nodule count during the study.

- Number of times escape medication has been used during the study.

- Average duration of a flare, reported by the patient, during the study.

- The IHS4 and HS-PGA, measured every visit during the study.

- Amount of clindamycin lotion use during the study.

- Difference in the cumulative dose of laser energy used.

Safety and tolerability:

- Number of adverse events during the study.

- Incidence and severity of all adverse events (according to medDRA) will be analyzed throughout the study.

Biopsy:

- Histopathological: diameter hair shaft, plugging, immunohistochemistry (keratin subtype expression, inflammatory markers), antimicrobial peptides (AMPs) expression in axillary skin before and after treatment (optional)

Study description

Background summary

Hidradenitis suppurativa (HS) is a chronic, recurrent and debilitating skin disorder, characterized by painful inflamed nodules, abscesses and tunnels, mainly in skin folds, such as the axillae, inguinal region and gluteal area. The primary cause of HS is an occlusion of the hair follicle. Several etiological factors (genetics, lifestyle, hormonal status and dysbiotic microbiota), induce immune activation of the outer root sheet keratinocytes, leading to acantohosis and hyperkeratosis of the infundibulum. This results in an occlusion of the terminal hair follicle, with subsequent dilatation and cyst formation. When rupture of the hair follicle occurs, an inflammatory response ensues, resulting in the typical clinical lesions of HS. HS severity can be

described using a classification system, such as the international hidradenitis suppurativa severity score system (IHS4). Previous studies showed that patients with mild to moderate HS are 95,3% of the total HS population. Although most patients have mild to moderate disease, clinical trials are focused on moderate and severe HS. This development has been noticed by patient advocate groups and they requested to an additional focus on milder cases of HS, to create more treatment options for this group.

Previous studies showed significant results in favor of laser hair removal in patient with HS compared to just topical therapy. Hair grows in three phases; first, there is active growth, called the anagen phase, Second, a hair goes in regression, called the catagen phase and third, at last a hair goes into a resting phase, called the telogen phase. This cyclic pattern of hair growth is significant because only hairs in the anagen phase are sensitive to the effect of hair laser therapy. Therefore, a patient needs several treatments to treat all hair follicles.

Considering the fact that HS arises in the hair follicle, we hypothesized that permanent removal of the hair could prevent further development of HS. Furthermore, in our experience, there is a high demand for laser hair removal therapy under patients with HS, but fundamental research to validate this has not been conducted yet.

Study objective

The primary objective of this study is to assess whether laser hair removal therapy improves the course and severity of mild to moderate HS, as assessed by the difference in IHS4 between groups over time between month 7 to month 12.

Study design

This study is a RCT with a duration of 12 months, which is divided into 2 periods of 6 months.

Intervention

The RCT consist of two periods of 6 months. From month 1 to month 6, the intervention group will undergo six monthly laser hair removal treatments in the axillae or inguinal area combined with clindamycin 1% lotion if needed, while the control group uses only clindamycin 1% lotion if needed. From month 6 to 12, there is a observational follow up of six months. During this period, both groups will use clindamycin 1% lotion if needed.

Study burden and risks

Patients will visit the out-patient clinic every month for a period of 12

months. Every visit a doctor will check the skin for HS lesions and the patient will fill out some questionnaires. The patients in the intervention group will undergo 6 hair laser removal treatments. This is a non-invasive treatment with minimal side effects, which mostly disappear within 24 hours. Prevention of side effects will be achieved by using correct settings of the laser device and the use of cooling and a narcotic creme. Compared to standard care, the amount of hospital visit is larger, but considering the high demand for laser hair removal therapy among patients, we think that a lot of patients want to participate.
Clindamycin 1% lotion if needed is standard of care and described in the guidelines of HS. Patients could experience some dry skin when using clindamycin 1% lotion.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- IHS4 mild to moderate, without tunnels in the axillae and/or inguinal area.
- HS activity in at least one axilla or at least one side of the inguinal area.
- Age 16 years and over.

Exclusion criteria

- If the patient is not able to give informed consent.
- If the patient is allergic to clindamycin lotion.
- If the patient uses systemic therapy for HS such as antibiotics or biologicals.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2023
Enrollment:	58
Type:	Anticipated

Medical products/devices used

Generic name:	Nd:YAG laser
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-07-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-06-2024
Application type:	Amendment
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
Other	Eudra CT 2022-003596-42
CCMO	NL83057.078.23