Long-term efficacy and safety of microwave ablation in the treatment of mild axillary hidradenitis suppurativa: a randomized intra-patient controlled trial

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Primary objective: To prospectively evaluate the lesion (AN-)count, i.e. abscesses, inflammatory nodules, and draining sinuses, in the axilla treated with MWA compared to the untreated contralateral axilla after six months.Secondary objectives: - To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON44256

Source
ToetsingOnline

Brief title
The WAVE trial

Condition

- Epidermal and dermal conditions

Synonym
acne ectopica, acne inversa

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 follicle, Hidradenitis suppurativa, Microwave ablation, Sweat gland

Outcome measures

Primary outcome

Clinical efficacy: Hidradenitis Suppurativa Clinical Response (HiSCR 50%),

based on the lesion count (AN count).

Secondary outcome

- PROMs: number of flares, numerical rating scale on pain and itch, patient

satisfaction;

- Average number of hair containing follicles (dermatoscopy);

- The extent of sweat production (starch-iodine test);

- Safety parameters (adverse events).

Study description

Background summary

Hidradenitis suppurativa (HS) is a chronic, inflammatory skin disease of the hair follicle, and is predominantly located in the axillary, inguinal and anogenital regions. Current treatment options for HS include systemic antibiotics, anti-TNF*, and surgery, which are used to treat the consequences rather than treating the primary pathogenesis of HS. With microwave ablation (MWA), using the heat generated from electromagnetic waves in the microwave energy spectrum, hair follicles and apocrine and eccrine glands in the (hypo)dermis are ablated through thermolysis. MWA was recently approved for the treatment of axillary hyperhidrosis (miraDry) and removal of axillary hair (miraSmooth). We hypothesize a beneficial and long-term (prophylactic) effect of MWA in HS patients.

Study objective

Primary objective:
To prospectively evaluate the lesion (AN-)count, i.e. abscesses, inflammatory nodules, and draining sinuses, in the axilla treated with MWA compared to the untreated contralateral axilla after six months.

Secondary objectives:
- To prospectively evaluate the AN-count in the axilla treated with MWA at month six relative to baseline.
- To prospectively evaluate the AN-count in the axilla treated with MWA at month three compared to the untreated contralateral axilla, i.e. early response.
- To prospectively assess the effect of MWA on the number of HS flares in the treated and untreated axillae.
- To evaluate patient-reported outcome measures (PROMs).
- To assess the average number of hair containing follicles in the treated area at month six relative to baseline.
- To assess the decrease of sweat production in the treated area at month six relative to baseline.
- To prospectively assess the safety and tolerability two weeks, three months, six months after treatment with MWA.
- Optional (separate consent): assessment of long-term efficacy and safety at month 12 and 36 after MWA treatment.

Study design

Randomized intra-patient controlled trial.

Intervention

Twenty patients will be randomly allocated to a one-sided single MWA treatment in one axillary region with a miraDry device.

Study burden and risks

Eligible patients will be recruited during routine clinical care in the department of Dermatology of the Erasmus MC and Havenziekenhuis. The study will be performed in the Erasmus MC. There is a total of 3 visits and an optional 2 visits which are incorporated in routine clinical care. Per subject a total number of 3 physical examinations and 3 starch-iodine tests will be performed. In addition, two tattoo ink spots (1 mm) will be placed in both axillary regions at baseline to assure identical measuring areas during the treatment and follow-up period. The ink spots will be removed by laser therapy at the end of the study. During the follow-up of 6 months participants will be asked to count the number of flares and the use of topical clindamycin 1% in a diary, and to take (self)photographs of the lesions.

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

Key inclusion criteria:
- Adult (* 18 years old) patients suffering from HS;
- Minimum of 3 AN-count located in each axilla;
- Maximum of 5 AN-count located in each axilla.

Exclusion criteria

Key exclusion criteria:
- >1 abscess or draining fistula per axillary area;
- AN-count * 5 in other regions than the axillary area;
- Surgical scars covering more than 25% of each individual axillary area;

- Previous successful use of laser or light therapy for hair removal in the axillary area;
- Use of botulinum toxin injections 6 months prior to randomization.
- Pregnancy (at time of treatment)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-10-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	23-08-2017
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	NL61979.078.17