Short term clinical efficacy of topical treatment with clindamycin-benzoyl peroxide gel compared with clindamycin lotion in mild to moderate Hidradenitis Suppurativa

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

Summary

ID

NL-OMON48051

Source
ToetsingOnline

Brief title
TOPIC

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: Acne inversa, Topical treatment

Outcome measures

Primary outcome

The frequency of flares (active lesions) during 12 weeks.

Secondary outcome

1. Clinical efficacy after 12 weeks.

2. Skin-related pain after 12 weeks.

3. Pruritus after 12 weeks.

4. Treatment satisfaction after 12 weeks and after an additional 4 week

follow-up.

5. Sustained efficacy after 4 week follow-up after end of treatment.

6. Diversity of the microbiome at baseline, 12 weeks and after an additional 4

week follow-up.

7. Resistance pattern at baseline, 12 weeks and after an additional 4 week

follow-up.

8. The short-term safety and tolerability of both treatments after 12 weeks.

Study description

Background summary

For mild and moderate HS topical clindamycin 1% is often prescribed for its

mild comedolytic and anti-inflammatory effects. The application of topical clindamycin has been studied in a both a clinical trial and a randomized control trail and was shown to be more effective compared with placebo. Topical clindamycin 1%/benzoyl peroxide 5% gel, is often used in the treatment for acne vulgaris. Benzoyl peroxide has antibacterial, anti-inflammatory, and comedolytic properties. The combination of Clindamycin and benzoyl peroxide was shown to be more effective compared with clindamycine alone. Moreover, the addition of benzoyl peroxide 5% to clindamycin reduces clindamycin resistance in acne vulgaris patients for Propionibacterium acnes.

Study objective

Therefore the primary objective of this study is to evaluate the effect of twice daily application of topical clindamycin1%/benzoyl peroxide 5% gel compared with the standard treatment with topical clindamycin1% lotion on the frequency of active lesions in mild to moderate HS.

Study design

This study is a randomized, assessor blinded, prospective active controlled intra-patient trial. Potentially eligible patients will be informed about the study procedures and will be given ample time to consider their decision. After obtaining informed consent patient will be screened for eligibility. Two affected contralateral anatomical regions will be randomised to clindamycin/benzoyl peroxide gel (Treatment A) of clindamycin 1% lotion (Treatment B) and followed for 12 weeks, with an additional follow-up visit after 4 weeks after end of treatment. Any other affected areas will be treated with clindamycin lotion 1% according to the current guidelines.

Intervention

Twice daily application of topical clindamycin1%/benzoyl peroxide 5% gel.

Study burden and risks

Patients will visit the hospital every 4 weeks for a duration of 16 weeks. On all visits patients will fill out a short questionnaire and physical examination will be performed by a blinded physician. Moreover, patients will be asked to complete a diary throughout the 16 weeks, to record active lesions. Swabs will be taken from both randomized anatomical area*s at baseline, after 12 and 16 weeks to assess, microbiome diversity and the resistance patterns. Swabs are safe and pose no risk to the patient Other risks for participating patients are minimal and consist of the occurrence of treatment related side effects and adverse events, including dryness, flaking and irritation of the treated skin. Benefits for patients may include an improvement of HS symptoms;

a reduction of the frequency of active 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

1. Age >=18 years
2. Mild to moderate HS defined as a HS-PGA of 2 or 3 with at least 2 lesions in each eligible anatomical area
3. A diagnosis of HS for more than six months prior to baseline
4. Able and willing to give written informed consent and to comply with the study requirements

Exclusion criteria

1. Contraindication for treatment with either clindamycin lotion 1% or clindamycin 1%/benzoyl peroxide 5% gel
2. Superinfection of HS lesions
3. Current or recurrent clinically significant skin condition in the HS treatment area other than HS.
4. Presence of other uncontrolled clinically significant major disease.
5. Pregnant and lactating women
6. The use of systemic antibiotics 14 days prior to inclusion
7. The use of topical antibiotics or Resorcinol cream in the eligible areas 14 days prior to inclusion.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-06-2019
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	DUAC
Generic name:	clindamycine 1% / benzoyl peroxide 5%

Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	28-05-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-06-2019
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
EudraCT	EUCTR2018-004338-13-NL
CCMO	NL68260.078.18