Treatment of Hidradenitis Suppurativa with a blue light (415 nm) and red light(633 nm) combination PDT

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Investigate the treatmentefficacy of a red light (633 nm) and blue light (425) combination PDT in HS.

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

Summary

ID

NL-OMON31302

Source
ToetsingOnline

Brief title
Hidradenitis blue-red light combination PDT

Condition

- Epidermal and dermal conditions

Synonym
acne inversa, hidradenitis suppurativa

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: blue, hidradenitis, PDT, red

Outcome measures

Primary outcome

Reduction Sartorius score

reduction unidimensional visual painscore

Secondary outcome

Time to improvement individual laesions

Time to improvement painscale scores

Treatment experience

satisfaction

side effects

visual improvements on photo's

Study description

Background summary

Hidradenitis Suppurativa is a chronic inflammation of follicles, primarily in the axillae and groin area. The disease manifests as clusters of chronic abscesses or boils that are extremely painful to the touch and may persist for years with occasional to frequent periods of inflammation.

Present treatment methods are: antibiotics, intralesional or systemic steroïds, surigical operation and other methods like oral anticonceptives, ALA-PDT . There are not many studies know that investigate PDT for HS. A combination therapy is only known for acne vulgaris. The properties of red (633 nm) and blue (425 nm) light complement each other in a way they can reduce the inflammation, pain and might prevent new lesions.

Study objective

Investigate the treatmentefficacy of a red light (633 nm) and blue light (425) combination PDT in HS.

Study design

single-blind prospective study.

Intervention

Every patient has at least one treatment- control combination with the same Hurley classification. Every Hurley- combination consist of a treatment area and a control are.
Treatment with: Omnilux Blue en Omnilux Revive.

Study burden and risks

Based on literature research and practical experience ewith the Omnilux Blue and Revive for PDT treatment, no serious adverse events are to be expected.

-eye damage: wearing goggles
-erythema: Immediately after treatment. Lasts for about half an hour
-Irritation, itch, burning sensation: normally a few hours, in some cases a few days
-Inflammation - In rare cases a temporarily eczema or folliculitis may appear. This will last for a few weeks.

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

Suffering from hidradenitis suppurativa. 18-45 years old. In case of oral medication/ anticonceptives: use of at least 6 months and intention te continue use during study.

Exclusion criteria

-Oral medication for HS in last 2 months
-In menopause or postmenopausal
-Intention to use anticonceptives
-Previous external or oral use of isotretinoine in last 6 months
-Oral/ local anti-inflammatory medication during the last 4 weeks
-Epilepsy
-Pregnancy, breastfeeding, intention to conceive
-Photosensitivity
-Use of photosensitive medication
-treatment for cancer in the past, history of skincancer, presence of premaligne lesions
-Use of anticoagulants, suffering from a clotting-disease.
-Surgical operations in the treatment areas in the past 6 months
-recently had PDT for HS
-Recent suntanning or planning to

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2007
Enrollment:	11
Type:	Actual

Ethics review

Approved WMO Date:	30-10-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL19440.060.07