Laser treatment for Hidradenitis Suppuritiva.

No registrations found.

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

Summary

ID

NL-OMON27641

Source
NTR

Brief title
N/A

Health condition

Hidradenitis Suppuritiva

Sponsors and support

Primary sponsor: Erasmus MC, department of Dermatology and department of Immunology
Burg. s' Jacobplein 51,
3015 CA Rotterdam,
The Netherlands
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

To determine the efficacy of Multiplex laser whether or not combined with Metvix in patients with mild to moderate HS.

Secondary outcome

1. To determine the percentage improvement of the lesions, the degree of pain and the degree of treatment satisfaction;

2. To determine the short-term side effects and tolerance of Multiplex laser whether or not combined with Metvix for the treatment of HS;

3. To determine the duration of remission during follow-up;

4. To dertermine changes of specific celpopulations.

Study description

Background summary

Observer-blinded intervention study.

The skin lesions of 20 patients with mild to moderate HS wil be treated on one site of the body with multiplex laser combined with methyl aminolevulinate and on the other site of the body with multiplex laser.

Study objective

The skin lesions of HS patients will significantly more improve after treatment with Multiplex laser combined with methyl aminolevulinate than after treatment with the only the multiplex laser.

Study design

1. Specific HS sartorius score: screening, week 2, 6, 10, 14, 18, 24;

2. Skinbiopt: screening at week 18;

3. VAS (pain, gravity of disease and patient satisfaction), DQLI;

4. Skin fotographs: screening, week 2, 10, 18, 24.

Intervention

Multiplex laser (PDL 6-8 J/m2, 10 ms, 7 mm and the 1064 nm Nd-YAG 30-40 J/m2, 40-50 ms, 7 mm) combined with methyl aminolevulinate (1 mm cream on and 5-10 mm around the lesion) versus multiplexlaser (same fluence).

Contacts

Public
Erasmus MC, department of Dermatology
Dr. Molewaterplein 50
H.H. Zee, van der
Dr. Molewaterplein 50
Rotterdam 3015 GE
The Netherlands
+31107043430
Scientific
Erasmus MC, department of Dermatology
Dr. Molewaterplein 50
H.H. Zee, van der
Dr. Molewaterplein 50
Rotterdam 3015 GE
The Netherlands
+31107043430

Eligibility criteria

Inclusion criteria

1. Male/female 18 years or older of age;

2. Active moderate to moderate hidradenitis suppurativa (Hurley stage 1 or 2).

Exclusion criteria

1. Patients with a photoallergie or hypersensitivity to the active substance methyl aminolevulinate;

2. Pregnant women.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2009
Enrollment:	20
Type:	Anticipated

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	NL1846
NTR-old	NTR1957

Register	ID
Other	eudra-CT nummer : 2009-015519-42
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A