Rosacea and the Subpurpuric pulsed dye laser treatment Efficacy

No registrations found.

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

Summary

ID

NL-OMON20185

Source
NTR

Brief title
RoSE

Health condition

Rosacea, Pulsed Dye Laser, Subpurpuric dose

Sponsors and support

Primary sponsor: Academic Medical Center, Department of Dermatology
Source(s) of monetary or material Support: Academic Medical Center, Department of Dermatology

Intervention

Outcome measures

Primary outcome

• Health Related Quality of Life (HRQoL) measurement as a patient reported outcome (PRO) by using the RosaQol, a rosacea-specific HRQoL questionnaire

• Blinded evaluation of photographs by using the Investigators Global Assessment (IGA)

Secondary outcome

• Blinded evaluation of photographs by

- using Clinician's Erythema Assessment (CEA)

- grading of severity of telangiectasia
Patient’s Global Assessment (PGA)

Study description

Background summary

PDL therapy is used worldwide for erythematotelangiectatic rosacea. Subpurpuric PDL treatment is characterized by using a fluence that is just below the purpura threshold of the patient. With these settings posttreatment side effects such as purpura can be avoided. Lasers and accompanying settings improved a lot since introduction, but optimal therapy parameters and intervals between treatments have not yet been decided.

Study objective

We hypothesize that the experimental 2-week interval will neither cause a difference in burden nor in risks. It probably will lead to better results and it has the advantage that the total duration of treatment is shorter.

Study design

Patients will be seen at screening and at 2 weeks or 8-weeks interval between the treatments, with a maximum of 4 treatments. Follow up 8-10 weeks ana 1 year after last treatment.

Intervention

Subjects receive subpurpuric Pulsed Dye Laser (PDL) treatments until their visible telangiectasia are disappeared with a maximum of 4 treatments, separated by either a 2-week interval (Arm 1) or an 8-week interval (Arm 2).

Contacts

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Eligibility criteria

Inclusion criteria

1. Subject has rosacea subtype 1 (erythematotelangiectatic) with at least 5 telangiectasia.

2. Subject is at least 18 years of age at baseline.

3. Subject has skin type I or II according to Fitzpatrick.

4. Subject can fill out a Dutch questionnaire or has a person willing to translate the questions in their own language.

5. Subject has voluntarily signed and dated an informed consent prior to any study related procedure and is willing to comply with the requirements of this study protocol which has been approved by an Institutional Review Board (IRB)/Independent Ethics Committee (IEC).

Exclusion criteria

1. Subject has steroid or other medication induced rosacea

2. Subject takes medicines that are known to trigger rosacea.

3. Subject has used systemic rosacea medication in the past 3 months.

4. Subject is pregnant.

5. Presence of dermatoses that might interfere with the rosacea or the evaluation of treatment results.

6. Subject has had facial laser-therapy less than 12 months before baseline or receives laser therapy beyond the study protocol during study.

7. Subject has used isotretinoin six months prior to the first treatment.

8. Subject is known to have a seizure disorder triggered by light.

9. Subject has atypical melanocytic lesion(s) on the face.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2013
Enrollment:	58
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 41694
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4661
NTR-old	NTR4804
CCMO	NL40799.018.12
OMON	NL-OMON41694

Study results