Rosacea and the Subpurpuric pulsed dye laser treatment Efficacy

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20185

Bron
NTR

Verkorte titel
RoSE

Aandoening

Rosacea, Pulsed Dye Laser, Subpurpuric dose

Ondersteuning

Primaire sponsor: Academic Medical Center, Department of Dermatology
Overige ondersteuning: Academic Medical Center, Department of Dermatology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• 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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2013
Aantal proefpersonen:	58
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41694
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten