Microneedling after reconstructive scarring

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30% improvement is the minimal effect found in previous microneedling studies, based on this studies we expect to find a 7.5 point improvement on the POSAS total score

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28278

Bron
NTR

Verkorte titel
MARS-trial

Aandoening

Abdominal scars after DIEP flap breast reconstruction

Ondersteuning

Primaire sponsor: Radboudumc and University of Applied Sciences Utrecht
Overige ondersteuning: Radboudumc, University of Applied Sciences Utrecht, sponsoring in kind of the microneedling device by distributor Dermapen Benelux

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patient experienced scar quality using the Patient Scar Assessment Scale (PSAS) total score of the POSAS.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Microneedling shows promising results on improving scar characteristics and overall scar opinion in acne and burn scarring. Because of this it is interesting to study the effect of microneedling on surgical scarring. The impact of donor site scarring after DIEP flap breast reconstruction and the growing demand for minimally invasive scar treatments urge the need for a study for this specific indication.
Objective: To investigate the effect of microneedling on the patient overall opinion of the abdominal scar quality after a DIEP flap procedure comparing the treated part and the untreated part of the scar.
Study design: a controlled split scar trial.
Study population: 30 women who have undergone a DIEP flap breast reconstruction in Radboudumc, after prophylactic or curative breast surgery in the past 18 months, but at least 6 months ago. Women have self-reported scar symptoms such as pain, itching, color, stiffness, thickness and irregularity or wish overall improvement of the scar quality.
Intervention: The procedure consists of 3 microneedling sessions using an electric-powered pen, performed on one abdominal scar half. The interval of the sessions is 4 weeks. Settings will be adjusted to participants comfort and the clinical visible uniform pin-point bleeding.
Control: The other half of the scar remains untreated.
Main study parameters: Patient experienced scar quality using the Patient Scar Assessment Scale (PSAS) total score of the POSAS. Secondary parameters are: patient experienced scar quality, patient satisfaction, subjective assessment of scar quality, objective scar quality and experienced side effects.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The microneedling device is applied with a CE class I marked device and will be used within the intended use. The risk of the study design, intervention, study population and social impact are negligible. The benefits of microneedling may have a positive effect on the whole abdominal scar, since we offer to treat also the untreated part of the scar after the study. We do not expect that the microneedling procedure pose a risk or burden to patients.

Doel van het onderzoek

30% improvement is the minimal effect found in previous microneedling studies, based on this studies we expect to find a 7.5 point improvement on the POSAS total score

Onderzoeksopzet

T0= baseline, before first microneedling session
T1= 12 weeks after third microneelding session
T2= 24 weeks after third microneedling session
T3= 9 months after third microneedling session

Onderzoeksproduct en/of interventie

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Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Have an abdominal scar resulting from a DIEP flap breast reconstruction in the past 18 months, but at least 3 months ago;
- Have a wish for improvement on pain, itching, color, stiffness, thickness, irregularity or overall scar quality of (at least 10 cm) the abdominal scar;
- Age equal or above 18 years;
- Dutch speaking, reading and writing;
- Able to provide informed consent;
- Fitzpatrick type I-III according to the classification of skin phototype (I-IV).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Are currently applying or receiving any form of scar therapy what needs to be continued during the study;

- Consider to undergo scar reconstruction surgery during the study;
- Are on chemotherapy or radiotherapy;
- Have a presence of skin cancers, warts, solar keratosis, or any skin infection in the abdominal scar area;
- Have keloid scarring in the abdominal scar area or the tendency to develop keloid scarring based on previous developed keloid scars;
- Are not willing to use sun protecting factor (SPF) for the period of 4 weeks after each microneedling session;
- Have an uncontrollable coagulation status;
- Are or become palliative or terminal;
- Have or develop a serious systemic disease;
- Are or become pregnant or have a wish to become pregnant during the study;
- Who are simultaneous participate in another scientific study interfering with the abdominal scar formation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	17-02-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8388
Ander register	CMO regio Arnhem Nijmegen : 2020-6208/NL72993.091.20

Resultaten