Treatment of surgical scars in breast reduction with laser device, to prevent scar hypertrophy.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON36674

Source
ToetsingOnline

Brief title
Laser treatment to prevent scar hypertrophy.

Condition

- Epidermal and dermal conditions
- Skin and subcutaneous tissue therapeutic procedures

Synonym
excessive scarring, hypertrophic scarring

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: hypertrophy, laser, scar, wound healing

Outcome measures

Primary outcome

Outcomes of the Vancouver Scar Scale (VSS) and POSAS score at 12 months after surgery.

Secondary outcome

Objective scar measures: volume (3D), width, height, colour.

Cosmetic appearance. The patient will rate the scar*s overall cosmetic aspect on a visual analogue scale. Two independent plastics surgeons will rate the overall aspect as well on basis of the photographs.

Complications.

Time course of scar formation using all parameter measures at earlier time points (10 days, 6 weeks, 3 and 6 months after surgery).

Study description

Background summary

Every trauma or surgery leaves a scar in the skin. Even thorough surgery and meticulous stitching can not prevent the formation of excessive scarring in predisposed individuals. It is thought that the kind of immune reaction influences the scar formation and can give them a raised and red appearance as seen in burn wounds. Patients often seek help to improve the functional and cosmetic impairments due to the excessive scarring.

Study objective

There are indications that early laser treatment of wounds can reduce scar formation. With the laser device the wound will be heated, which is thought to be responsible for a reduced inflammatory reaction and hence for a reduced scar

formation. The purpose of this study is to determine whether treatment of surgical wounds directly after closure with the EkkyLite* laser system will improve clinical and cosmetic appearance relative to untreated wounds in women who undergo breast reduction surgery.

Study design

In this study the cosmetic and physical appearance of scars are evaluated in patients undergoing breast reduction surgery. Wounds treated with laser therapy with the EkkyLite system are compared with untreated wounds within the same subject. The study is a prospective, randomized, controlled, left-right comparison study.
The enrollment period is 1 year and the follow-up period is 1 year.
Patients are randomly assigned to one of two treatment groups:
Group 1: Laser treatment of right lateral and left medial infra-mammary scar
Group 2: Laser treatment of left lateral and right medial infra-mammary scar

Intervention

The laser treatment that will be assessed in this study will be used at the end of the surgical operation only, directly after closure of the surgical wound. Breast reduction surgery is performed exactly as is customary. The wound is closed with the normal sutures; Monocryl® 3.0 subcutaneously and Monocryl® 4.0 intra-cutaneously. After closure a part of the surgical wounds at the underside of both breasts (left and right) will be treated with the EkkyLiteTM laser device. Which part exactly is treated shall be decided by randomization.
The laser beam will be applied spot-by-spot. The power and duration of the laser shots, which have to correspond to the size of the spot used (20x4 mm), will be adjusted.
Fluence will be adjusted to patient skin phototype:
* 110J/cm² to skin phototype I to III (shot duration of 13 seconds)
* 85J/cm² to skin phototype IV (shot duration of 10) seconds

Study burden and risks

The risk of the treatment is very small. No adverse effects of the treatment have been reported yet. The possibility of overheating (burning) of the tissue are prevented by the system itself. Treatment and follow-up is as normal. The effectiveness of the EkkyLiteTM laser has been demonstrated in breast enlargement surgery and abdominal surgery. However, scientific evidence that excessive hypertrophic scar tissue formation is prevented by laser treatment with the EkkyLiteTM device is still lacking, it can not be assumed on forehand that the patient will benefit from the treatment. The only extra burden for the patient is the time invested for filling in questionnaires at four follow-up time points.

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

- Patients undergoing breast reduction surgery with a wise pattern technique.
- Older than 18 years of age.
- Willing to participate.

Exclusion criteria

- Dark skin (skin types V or VI, Fitzpatrick Skin Typing Test)
- Pregnant woman
- Malignant tumor skin disease
- Bacterial or viral infectious skin disease
- Immunosuppression (linked to a pathology or specific treatment)

- BMI > 27
- Hart and/or lung disease

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Laser device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	28-07-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL35102.029.11