

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

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Epidermal and dermal conditions
<b>Study type</b>	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 EkkyLite™ 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/cm<sup>2</sup> to skin phototype I to III (shot duration of 13 seconds)

\* 85J/cm<sup>2</sup> 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 EkkyLite™ 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 EkkyLite™ 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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### Scientific

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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)

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- 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**

<b>Register</b>	<b>ID</b>
CCMO	NL35102.029.11