# The effect of microneedling on abdominal scarring after DIEP flap breast reconstruction

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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 after 9 months of follow up.

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| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Skin and subcutaneous tissue disorders NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON55074

**Source**
ToetsingOnline

**Brief title**
MARS-trial

### Condition

- Skin and subcutaneous tissue disorders NEC

**Synonym**
scarring, scars

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W,Hogeschool Utrecht,Dermapen Benelux

## Intervention

**Keyword:** breast reconstruction, DIEP flap, microneedling, scars

## Outcome measures

### Primary outcome

Patient experienced scar quality for the treated scar half compared to the untreated scar half, using the Patient Scar Assessment Scale (PSAS) total score of the POSAS.

### Secondary outcome

Secondary parameters are: patient experienced scar quality, patient satisfaction, subjective assessment of scar quality, objective scar quality (color, thickness and elasticity measured with the Dermalab) and experienced side effects.

# Study description

### Background summary

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.

### Study 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 after 9 months of follow up.

### Study design

A controlled split scar trial in Radboudumc.

**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 endpoint of uniform pin-point bleeding.
Control: The other half of the scar remains untreated.

**Study burden and risks**

The microneedling device is applied with a CE 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 an extra risk or burden to patients.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

### Inclusion criteria

- 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 with regard to the abdominal scar;
- Age equal of above 18 years;
- Dutch or English speaking, reading and writing;
- Is able to provide informed consent IC;
- Fitzpatrick type I-III

### Exclusion criteria

- Are currently applying or receiving any form of scar therapy what needs to be continued during the study;
- Have permanent filler injections in the abdominal scar;
- Have the desire 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 pregnant or have the wish to become pregnant during the study;
- Who are simultaneous participate in another scientific study interfering with the abdominal scar formation.

## Study design

### Design

**Study type:** Interventional
Masking: Open (masking not used)

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| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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| Recruitment status: | Completed |
| Start date (anticipated): | 05-10-2020 |
| Enrollment: | 30 |
| Type: | Actual |

### Medical products/devices used

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| Generic name: | Dermapen |
| Registration: | Yes - CE intended use |

## Ethics review

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| Approved WMO Date: | 04-08-2020 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 15-10-2020 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 25-01-2021 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 27-07-2021 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# 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 | NL72993.091.20 |
| Other | NL8388 |

# Study results

Date completed: 13-02-2022

Results posted: 12-12-2024

Actual enrolment: 30

**First publication**
12-12-2024