

Percentage of receptors responsible for sensibility in the breast versus abdomen (at the level of the skin).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21816

Source

Nationaal Trial Register

Brief title

ReBB

Health condition

sensibility breast, sensibility abdomen, breast reconstruction, breast cancer, receptor

Sponsors and support

Primary sponsor: Zuyderland Medical Centre

Maastricht University Medical Centre

Source(s) of monetary or material Support: Maastirch University Medical Centre

Intervention

Outcome measures

Primary outcome

percentage of receptors responsible for the sensibility in the skin.

Secondary outcome

The difference in percentage of receptors between breast, nipple, areola and abdomen.

Study description

Background summary

By taking biopsies of the skin of the breast and the abdomen we will analyze the difference in percentages of receptors responsible for the sensibility. This can be of great value for the expected results concerning the sensibility after a breast reconstruction.

Study objective

The percentage of receptors responsible for sensibility in the breast (and nipple) differ from the percentage of receptors in the abdominal skin.

Study design

biopsy during the operation.

Intervention

During the mastectomy 6 biopsies of 5mm will be taken of the skin that will be removed during the mastectomy.

During the abdominal surgery (DIEP, lowerbodylift, abdominoplasty) 2 biopsies of 5mm will be taken of the skin that will be removed during this surgery.

The biopsies will be analyzed and the percentage of receptors responsible for the sensibility in the skin will be compared.

Contacts

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Eligibility criteria

Inclusion criteria

- female - Age of at least 18 years
- Mastery of the Dutch language in word and writing.
- Informed consent for participation in the research
- biopsy of the tissue is possible from the tissue that will be removed during a mastectomy or abdominal operation (lowerbodylift, DIEP or abdominoplasty)

Exclusion criteria

- clinical abnormalities are visible on the nipple
- Mastitis, ulcerations on the breast or a T4-tumor. r.
- Suspicion of M. Paget
- On imaging the tumor is located in less than 2cm distance of the nipple.

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2018
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion	
Date:	30-09-2018
Application type:	First submission

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
NTR-new	NL7281
NTR-old	NTR7514
Other	: METCZ20180082

Study results