

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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21816

Bron

Nationaal Trial Register

Verkorte titel

ReBB

Aandoening

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

Ondersteuning

Primaire sponsor: Zuyderland Medical Centre

Maastricht University Medical Centre

Overige ondersteuning: Maastricht University Medical Centre

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

percentage of receptors responsible for the sensibility in the skin.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

biopsy during the operation.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	30-09-2018
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	NL7281
NTR-old	NTR7514
Ander register	: METCZ20180082

Resultaten