Patient satisfaction after oncoplastic breast surgery

No registrations found.

Ethical review Positive opinion **Status** Recruiting

Health condition type -

Study type Observational non invasive

Summary

ID

NL-OMON20774

Source

NTR

Brief title

TOBO

Health condition

breast cancer breast conserving surgery onocplastic surgery Breast Q satisfaction

Sponsors and support

Primary sponsor: Zuyderland Medical Centre

Source(s) of monetary or material Support: Zuyderland-Maastro Grant

Intervention

Outcome measures

Primary outcome

satisfaction of the breast after breast conserving therapy with reconstruction

Secondary outcome

difference regarding the satisfaction between the 2 groups (with and without reconstruction) difference regarding the satisfaction between before and after the adjuvant radiotherapy postoperative complications

Study description

Background summary

We will use the Breast-Q questionaire to investigate the patients' satisfaction concerning her breast after oncoplastic breastreconstruction. We will compare this outcome with the satisfaction of patients that receive a breast conserving surgery without reconstruction.

Study objective

Patients that receive breast conerserving therapy due to breastcancer with an oncoplastic reconstruction by the plastic surgery are more satisfied with their breast compared to patients receiving breast conserving therapy without a reconstruction.

Study design

preoperative

postoperative, before the adjuvant radiotherapy

postoperative, 3 months after the adjuvant radiotherapy

postoperative, 12 months after the adjuvant radiotherapy

Intervention

- Patients that receive breast conserserving therapy due to breastcancer with an oncoplastic reconstruction by the plastic surgery
- Patients that receive breast conserving therapy due to breast cancer without a reconstruction.

Contacts

Public

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Eligibility criteria

Inclusion criteria

- -female
- Age of at least 18 years
- Patient will undergo a curative breast-conserving surgery due to breast cancer in the affected breast
- Mastery of the Dutch language in word and writing.
- Informed consent for participation in the research

Exclusion criteria

- -Intellectual limitation to such an extent that it can be expected that the interpretation and / or completion of the questionnaires is a problem.
- -Previous radiotherapy on the affected chest

Study design

Design

Study type: Observational non invasive

Intervention model: Parallel

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Control: Active

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-02-2018

Enrollment: 110

Type: Anticipated

Ethics review

Positive opinion

Date: 13-12-2017

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 NL6667 NTR-old NTR6901 Other : Z2017135

Study results