# Patient Reported Outcome Measures (PROMs) in breast reconstruction: a prospective cohort study.

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| **Ethical review** | Not approved |
| **Status** | Will not start |
| **Health condition type** | Breast neoplasms malignant and unspecified (incl nipple) |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON40835

**Source**
ToetsingOnline

**Brief title**
PROMs in breast reconstruction

### Condition

- Breast neoplasms malignant and unspecified (incl nipple)

**Synonym**
breast reconstruction, mamma reconstruction

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** HagaZiekenhuis
**Source(s) of monetary or material Support:** geen geldstroom

## Intervention

**Keyword:** breast cancer, breast reconstruction, patient reported outcome measures, PROMs

## Outcome measures

### Primary outcome

The differences in pre- and postoperative scores of well-being and satisfaction

of the patient's. This will be scored by the use of the Breast-Q questionnaire.

### Secondary outcome

Differences in pre- and postoperative scores, compared wtih the different

surgical techniques:

- DIEP-method

- LD-method

- LD-method with tissue expander/protheses

- Prothese

- Tissue expander with prothese

# Study description

### Background summary

One may wonder whether a breast reconstruction after mastectomy is a medically necessary procedure. In a non-medical necessary intervention, the effectiveness of the treatment may be difficult to determine. Because ther is limited evidence for the effectiveness of treatment, there is a risk of suboptimal care, unnecessary costs and patient will have risk of complications due to unnecessary surgeries. Patient reported outcome measures are a instrument to measure whether the procedure will benefit the patient. The patient is asked to answer a questionnaire, the Breast-Q questionaire will be used in this study. The Breast-Q questionnaire is divided into 2 domains: quality of life and satisfaction. Usinn this questionnaire will help us to answer the question: What is the effectiveness of breast reconstruction (quality of life and satisfaction) from the perspective of the patient?

### Study objective

The aim of this study is to determine the effectiveness of the treatment (breast reconstruction) from the perspective of the patient's. By examining the results, the impact on the well-being and satisfaction, we will be able to customize the reconstruction to the needs of the woman and provide het with the best possible guidance, treatment and care.

### Study design

Prospective cohort study.

### Study burden and risks

The participant may not experience any personal benefit of the study, as it will take time before conclusions can be drawn from the collected data. The expectation is that if the objectives of the study have been achevied, the department will be able to optimize the treatment, support and care for future patients.
Answering questionnaires may be a confrontational experience. This will be explained during the recruitment of the participant, so that she has time to consider this aspect of the study. Of course the participant can always withdraw from the study.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

Women in need of a mastectomy or who had a mastectomy in the past and eligible for a breast reconstruction.

### Exclusion criteria

Women who are not able to speek Dutch

## Study design

### Design

**Study type:** Observational non invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Health services research |

### Recruitment

NL

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|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 260 |
| Type: | Anticipated |

# Ethics review

Not approved

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|---|---|
| Date: | 20-02-2015 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

# 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 | NL49573.098.14 |