# Patient satisfaction after mastectomy with immediate breast reconstruction.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON23201

**Source**
NTR

**Health condition**

borstkanker, patienttevredenheid breast cancer, tissue expander, patient satisfaction

### Sponsors and support

**Primary sponsor:** Atrium MC Parkstad
Henri Dunantstraat 5
6419 PC Heerlen
tel. (045) 576 66 66
zelf gefinancierd
**Source(s) of monetary or material Support:** Atrium MC Parkstad
Henri Dunantstraat 5
6419 PC Heerlen
tel. (045) 576 66 66
zelf gefinancierd

### Intervention

### Outcome measures

**Primary outcome**

Patient satisfaction.

### Secondary outcome

Complications afterwards due to operation:

1. Infection;

2. Hematoma.

Complications due to adjuvant treatment:

1. Fibrosis;

2. Capsular contracture;

3. Poor wound healing.

## Study description

### Background summary

For patients with breast cancer who are not applicable for breast-saving treatment (because of tumor characteristics), who prefer an amputation or who undergo a prophylactic amputation an immediate breast reconstruction is a standard offer. A patient may choose, in consultation with the plastic surgeon, between an autologous reconstruction or placement of a prosthesis. In this study only the tissue expanders will be taken into account. The tissue expander will be placed subpectoral and is, after sufficient outpatient filling, replaced for a definitive prosthesis. All patients with a tissue expander/prosthesis placed in the Atrium Medical Centre Parkstad in the period of January 2008 until July 2011 will be taken into account. The main goal of this research is to examine whether patients are satisfied and whether the complications during or after treatment are acceptable. Patients' satisfaction will be reviewed by means of a self-made questionnaire. Complications will be reviewed from the patients' medical report.

### Study objective

For patients with breast cancer who are not applicable for breast-saving treatment (because of tumor characteristics), who prefer an amputation or who undergo a prophylactic amputation an immediate breast reconstruction is a standard offer. A patient may choose, in consultation with the plastic surgeon, between an autologous reconstruction or placement of a prosthesis. In this study only the tissue expander/prosthesis will be taken into account. During this operation a tissue expander is placed after the mastectomy. After sufficient outpatient filling, the tissue expander is replaced for a definitive prosthesis. The main goal of

this research is to examine whether patients are satisfied and whether the complications during or after treatment are acceptable. Whenever the satisfaction is low it is essential to examine which factors contribute or have contributed to this dissatisfaction. It is important to examine whether the dissatisfaction is due to complications or due to other patient factors.

**Study design**

During the study patients will be contacted once by means of a questionnaire. Whenever there is no response after three weeks the patient will be contacted by telephone to remind her. All questionnaires received until June/ July 2012 will be included. The study will end in July 2012.

**Intervention**

In this study patients who received a tissue expander in the Atrium Medical Centre Parkstad will be included. The tissue expander is placed subpectoral and filled with saline infusion. Whenever there is enough stretching of the skin a definitive prosthesis is placed. The main outcome of this study is the patient satisfaction after placement of a tissue expander and definitive prosthesis. This will be reviewed by means of a self-made questionnaire. Patients who received a tissue expander in the Atrium Medical Centre Parkstad between January 2008 and July 2011 will be included. A control group will not be included. Complications will be reviewed from the patients' medical report.

## Contacts

**Public**
Atrium MC Parkstad<br>
Henri Dunantstraat 5
C. Scheeren
Heerlen 6419 PC
The Netherlands
+31 (0)45 5766666
**Scientific**
Atrium MC Parkstad<br>
Henri Dunantstraat 5
C. Scheeren
Heerlen 6419 PC
The Netherlands
+31 (0)45 5766666

## Eligibility criteria

## Inclusion criteria

In this cohort study patients with unilateral breast reconstruction (by tissue expander) or bilateral breast reconstruction (by tissue expander) will be taken into account. Timing of bilateral reconstruction may be synchronous or metachronous. Our goal is to include 100 patients who received an immediate breast reconstruction in the period of January 2008 until July 2011. Patients with breast cancer who are not applicable for breast-saving treatment (because of tumor characteristics), who prefer an amputation or who undergo a prophylactic amputation will be taken into account. Patients who lost their tissue expander or prosthesis because of complications will also be taken into account.

## Exclusion criteria

Patients who received a definitive prosthesis elsewhere than the Atrium Medical Centre Parkstad will be excluded. Other criteria for exclusion include patients with other reconstructions than the tissue expander.

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Factorial |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 14-11-2011 |
| Enrollment: | 100 |
| Type: | Actual |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 16-11-2011 |
| 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 | NL3000 |
| NTR-old | NTR3148 |
| Other | : 11-N-89/III |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A