

Patient satisfaction after mastectomy with immediate breast reconstruction.

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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...

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

Samenvatting

ID

NL-OMON23201

Bron

NTR

Aandoening

borstkanker, patienttevredenheid breast cancer, tissue expander, patient satisfaction

Ondersteuning

Primaire sponsor: Atrium MC Parkstad

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zelf gefinancierd

Overige ondersteuning: Atrium MC Parkstad

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patient satisfaction.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	14-11-2011
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	16-11-2011
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	NL3000
NTR-old	NTR3148
Ander register	: 11-N-89/III
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A