Breast Reconstruction In One Stage

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The aim of this study is to compare clinical outcomes and cost-effectiveness of two procedures for skin sparing mastectomy with implant reconstruction in a randomized clinical trial. The currently preferred two-stage breast reconstruction with...

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

Samenvatting

ID

NL-OMON27085

Bron
Nationaal Trial Register

Verkorte titel
BRIOS Study

Aandoening

Skin sparing mastectomy with implant reconstruction is frequently applied in breast cancer patients. Psychological outcome greatly improves when immediate breast reconstruction is performed after mastectomy. However, due to inadequate soft tissue coverage of the implant current direct implant procedures after skin sparing mastectomy are ineffective and often lead to revision surgery. Hence, a two-stage procedure, where tissue expanders are used as a first step and definitive implants are placed in a second procedure, is presently the preferred method. Still, each surgical procedure involves patient discomfort, multiple times of tissue expander filling, health risks and costs. Recently, a novel one-step procedure with the use of a collagen matrix inlay has been introduced. The method solves the problem of poor soft tissue coverage over the implant and positive results of this procedure have been reported. Up to date this new method has not been evaluated in a prospective randomized trial.

Ondersteuning

Primaire sponsor: VUMC
Overige ondersteuning: Pink Ribbon
NuthsOhra

LifeCell

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint of the study is the quality of life as measured by a specific breast related questionnaire (BREAST-Q) at one year after placement of the permanent prosthesis. This questionnaire was elected because it is especially suitable and valid for the post-mastectomy population.

Toelichting onderzoek

Doel van het onderzoek

The aim of this study is to compare clinical outcomes and cost-effectiveness of two procedures for skin sparing mastectomy with implant reconstruction in a randomized clinical trial. The currently preferred two-stage breast reconstruction with implantation of a tissue expander during a first, and placement of a breast prosthesis during a second surgery will be compared to the novel one-stage immediate breast reconstruction, where implants are combined with a collagen matrix inlay (Strattice™).

The use of a collagen matrix in combination with definitive implants in immediate breast reconstruction after skin sparing mastectomy is a good one-stage alternative for the traditional two-stage procedure because we think it

I. has the same or a lower complication rate;

II. gives equal or a better cosmetic result;

III. is less painful to the patient;

IV. Is more cost-effective.

Onderzoeksopzet

The follow-up moments will be arranged as following:

One-step procedure:

Surgery - 2 weeks post-op - 6 weeks – 3 months - 6 months – 12 months post-op.

Two-step procedure:

Tissue Expander - Fillings – Implant – 2 weeks – 6 weeks – 3 months - 6 months – 12 months post-op.

Onderzoeksproduct en/of interventie

Patients whom are eligible for the study and give informed consent will be operated by a plastic surgeon. Skin sparing mastectomy and implant reconstruction will be performed in all patients. Patients will be randomized to treatment group 1 or 2 three days before the mastectomy. In treatment group 1 a tissue expander will be placed during a first surgery, and abreast prosthesis will be placed during a second surgery. In the time between the first and second surgery the tissue expander will be filled repeatedly.

In treatment group 2, patients will undergo a skin sparing mastectomy with immediate placement of a breast implant combined with a collagen matrix sheet (Strattice™).

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Females are included if they meet the following criteria:

■ women with the BRCA 1/2 gen mutation who will undergo prophylactic treatment

■ intended to undergo a skin sparing mastectomy

■ willing and able to participate;

■ aged 18 and over;

■ able to provide informed consent and

■ able to complete questionnaires.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are:

■ women with a body mass index > 30

■ woman who need a too large breast size according to the specialist

■ woman who receive a polyurethaan implant

■ women who did not quit smoking two weeks before surgery

■ oncologic patients who have to receive post-operative radiotherapy

■ pregnancy or planning a pregnancy during the study;

■ ongoing severe psychiatric illness or mental retardation;

■ evidence of alcohol and/or drug abuse;

■ inability to complete the questionnaires;

■ local or general infection which could jeopardize the surgical objective;

■ extensive local inflammatory reactions;

■ proven or suspected hypersensitivity to materials;

■ immunosuppressive pathologies.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2013
Aantal proefpersonen:	140
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	08-10-2015
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	NL5337
NTR-old	NTR5446
Ander register	: PRHC-2012-RS01-version 4

Resultaten