Breast Reconstruction In One Stage

No registrations found.

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

Summary

ID

NL-OMON27085

Source
Nationaal Trial Register

Brief title
BRIOS Study

Health condition

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.

Sponsors and support

Primary sponsor: VUMC
Source(s) of monetary or material Support: Pink Ribbon
NuthsOhra
LifeCell

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Complication rate (e.g. infection, implant loss, seroma, contraction of the breast), aesthetic outcome (as measured by a panel of experts at one year after placement of the permanent prosthesis), pain, and patient burden with regard to the number of procedures and time invested are secondary outcomes.

Study description

Study objective

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.

Study design

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.

Intervention

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™).

Contacts

Public
VU University Medical Center - Dept. of plastic, reconstructive and hand surgery - Room Z4D130

Rieky E. Dikmans
P.O. Box 7057

Amsterdam 1007 MB
The Netherlands
Tel: +31(0)20 444 0256
Scientific
VU University Medical Center - Dept. of plastic, reconstructive and hand surgery - Room Z4D130

Rieky E. Dikmans
P.O. Box 7057

Amsterdam 1007 MB
The Netherlands
Tel: +31(0)20 444 0256

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2013
Enrollment:	140
Type:	Actual

Ethics review

Positive opinion

Date:	08-10-2015
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	NL5337
NTR-old	NTR5446
Other	: PRHC-2012-RS01-version 4

Study results