Skin sparing mastectomy with implant reconstruction: clinical outcomes and cost effectiveness of reconstruction in one stage with the use of a collagen matrix. A randomized clinical trial.

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A novel one-stage procedure where definitive implants are combined with a collagen matrix is compared to the traditional two-staged procedure where a tissue expander is placed before an implant. Our hypotheses are the following:The use of a collagen...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39753

Source
ToetsingOnline

Brief title
Skinsparing mastectomy with immediate implant reconstruction.

Condition

- Other condition
- Breast therapeutic procedures

Synonym
Borstkanker, breast reconstruction.

Health condition

Borstreconstructies.

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Pink Ribbon

Intervention

Keyword: Breast reconstruction, Collagen matrix, Implant, Skin sparring mastectomy

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) pre-operative and 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. In addition measure sexual health with questionaires before surgery and 12 months after surgery. 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. In addition, we look at cost-effectiveness. The esthetic outcome will be scored from pictures pre-operatively and one year post-operatively following the four point Harris breast scale (excellent-good-fair-poor) by the patient and a surgeonspanel.

Secondary outcome

Secondly we look at the cost-effectiveness of the procedures. The cost-effectiveness using the Dutch tariff QALYs will be calculated based on the

EQ-5D.

Study description

Background summary

Psychological outcome greatly improves when immediate breast reconstruction is performed after mastectomy. The traditional method for breast reconstruction after skin sparing mastectomy is a two-stage procedure where tissue expanders are used as a first step and definitive implants are placed in a second procedure. Each surgical procedure involves patient discomfort, multiple times of tissue expander filling, health risks and costs. It is advantageous if immediate breast reconstruction can be performed in a single procedure. Several direct implant one-stage procedures are known. They either provide full muscle coverage, with the disadvantage of high placement of prosthesis, needing revision surgery, or they provide poor coverage in the lower portion of the prosthesis. The use of a collagen matrix- an innovative approach in the one-stage operation technique - solves this problem. The technique involves insetting a sheet of collagen matrix between the infra mammary fold and the inferior border of the pectoralis major which leads to precise control of the inframammary fold, breast shape and lateral breast border. This results in a complete coverage of the implant without resorting to additional muscle or fascial elevation and better esthetical outcome. Collagen matrix can successfully be used in conjunction with breast implants to achieve an aesthetically pleasing result in one stage primary breast reconstruction, providing good soft tissue cover at the time after. The use of a tissue expander and its associated risks and costs are eliminated.

Study objective

A novel one-stage procedure where definitive implants are combined with a collagen matrix is compared to the traditional two-staged procedure where a tissue expander is placed before an implant.
Our hypotheses are the following:
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
1. Has the same or a lower complication rate.
2. Gives equal or a better cosmetic result.
3. Is less painful to the patient.
4. Is more cost-effective.

Study design

The study is a prospective multicenter, single blinded, randomized controlled clinical outcomes study. Randomization is stratified for all centers and divided over time in blocks. A statistician will prepare the randomization in advance. Before the operation is planned randomization takes place with closed numbered envelopes. Four academic centers and three peripheral hospitals in the Netherlands will participate coordinated by the principle investigator.

Intervention

1. Two stage breast reconstruction after skin sparing mastectomy, with placing of a tissue expander in the first, and implantation of a breast implant in the second stage.
2. One stage immediate breast reconstruction where implants are combined with a collagen matrix inlay.

Study burden and risks

The risk of complications will be comparable too the normal procedures. The extra burden for the patient includes the completion of questionnaires at each visit. The great benefit of participating in his study is that patients will be monitored closely and therefore the surgeon can follow the post-operative time closely. The big incentive for participating on the study is that women can finish their treatment earlier and hopefully with a better esthetical outcome only when randomized in the one stage procedure. The rest of the patients will receive the standard surgical treatment and after care for their condition.

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

Female patients from the participating hospitals are included if they meet the following criteria: willing and able to participate; aged 18 and over; able to provide informed consent and to complete questionnaires. Women who meet the inclusion criteria are informed about the study by their doctor and recieve a patientletter. There will be the possibility to ask further questions. Patients are included after signing the informed consent.

Exclusion criteria

Exclusion criteria are: 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:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-05-2013
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	03-12-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL41125.029.12