BRALAV-study: Breast Reconstruction; Added Layer, Added Value?

Published: 16-06-2014
Last updated: 20-04-2024

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 customary method for one-stage breast reconstruction with...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40855

Source
ToetsingOnline

Brief title
BRALAV-Study

Condition

- Other condition
- Breast therapeutic procedures

Synonym
Breast cancer, breast reconstruction

Health condition

Borstreconstructies

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Er is bij NuthsOhra een beurs aangevraagd

Intervention

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

Outcome measures

Primary outcome

The primary endpoint of the study is the number of reoperations as a result of complications within the first post-operative year

Secondary outcome

Secondary outcomes are: quality of life as measured by a specific breast related questionnaire (BREAST-Q), general quality of life measured with the EQ-5D, complication rate, aesthetic outcome and pain. The BREAST-Q will be administered pre-operatively and at one year after surgery, The EQ-5D is administered every 3 months to collect cost data. Based on these data QALYs will be calculated using the Dutch tariff.

Study description

Background summary

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 often lead to revision surgery. Recently, a novel one-step procedure with the use of an acellular dermal matrix (ADM) 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.

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 customary method for one-stage breast reconstruction with implantation of a direct implant will be compared to the novel one-stage immediate breast reconstruction where implant is placed with an acellular dermal matrix (ADM) inlay. We hypothesize that the addition of ADM in immediate implant-based breast reconstruction after skin sparing mastectomy is advantageous because it:
I. has the same or a lower re-operation rate;
II. gives a better cosmetic result;
III. is more cost-effective.

Study design

A prospective multicenter, randomized controlled clinical outcomes study.

Intervention

Eligible patients, who 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 at least three days before the mastectomy. In treatment group 1 a direct breast implant will be placed after the mastectomy. In treatment group 2, placement of the implant will be combined with insertion of an ADM sheet.

Study burden and risks

With regard to the intervention no extra burden will be placed on the patient. There are no extra risks involved in either operation as both methods are already being used by the participating surgeons. The extra burden for the patient comprises the time for completion of questionnaires at each visit.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Females are included if they meet the following criteria:
* willing and able to participate;
* aged 18 and over;
* able to provide informed consent and
* able to complete questionnaires.

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:	Will not start
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	Collagen Matrix
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-06-2014
Application type:	First submission
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	NL48218.029.14