Seroma reduction and drain free mastectomy - SARA trial

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To prove that omitting drains after mastectomy and flap fixation does not contribute to higher incidence of seroma formation and therefore reducing patient disutility such as seroma aspirations and visits to the outpatient clinic, as well as...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON48302

Source
ToetsingOnline

Brief title
SARA

Condition

- Breast therapeutic procedures

Synonym
fluid collection, seroma formation

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Geen subsidie

Intervention

Keyword: Drain free, Mastectomy, Seroma reduction

Outcome measures

Primary outcome

Patients undergoing seroma aspiration (clinically significant seroma (CSS)).

Secondary outcome

To assess

1. Number of invasive interventions related to seroma or wound healing defined as: every aspiration of clinically significant seroma, incision and drainage of abscess or in-fected seroma and/or operative debriding of the wound.

2. Surgical site infection (SSI) rate, defined as redness, pain, heat or swelling at the site of the incision or by the drainage of pus. Infection rate will be measured by A) the need for antibiotics, B) seroma aspiration due to infection or C) surgical drainage during the first six postoperative months.

3. Cosmesis rated by the patient using the numeric rating scale (NRS) every planned outpatient clinic visit.

4. Quality of life measured using the SF-12 Health Survey

5. The number of outpatient department visits, measured during the first six months postoperative.

6. Experienced wound pain and pain at the drain site by the patient using the NRS.

Study description

Background summary

Seroma formation, a collection of serous fluid containing blood plasma and/or lymph fluid, is a common complication in breast cancer surgery and can lead to delayed wound healing, infection, skin flap necrosis, patient discomfort and repeated visits to the outpatient clinic and therefore extensive research has been done to further elucidate the pathophysiology and prevention of seroma formation. Promising results have resulted from studies focusing on flap fixation in order to reduce the incidence of seroma and seroma aspirations. Mastectomy with flap fixation is becoming standard practice and is currently combined with closed-suction drainage. Closed-suction drainage is considered gold standard for reducing seroma formation after breast cancer surgery. However, evidence shows that closed-suction drainage is insufficient in preventing seroma formation. One might wonder if there is still a place for closed-suction drainage after mastectomy if flap fixation is performed. The promising results in flap fixation could exclude drainage systems in breast cancer surgery. However, the available data consist of small case series and therefore a large randomized controlled trial is needed for it to be widely implemented.
To our knowledge, no randomized controlled trial has been conducted comparing flap fixation with and without closed-suction drainage with seroma aspiration as the primary outcome.
We hypothesize that flap fixation with closed suction drainage does not cause a significant lower incidence of seroma aspirations, when compared to flap fixation alone. We also expect that patients without drainage will experience significantly less discomfort and comparable rates of surgical site infections.

Study objective

To prove that omitting drains after mastectomy and flap fixation does not contribute to higher incidence of seroma formation and therefore reducing patient disutility such as seroma aspirations and visits to the outpatient clinic, as well as reducing seroma related wound complications.

Study design

Prospective randomized controlled trial

Intervention

1. Mastectomy with flap fixation using ARTISS tissue glue and mattress sutures with closed suction drainage
2. Mastectomy with flap fixation using ARTISS tissue glue and mattress sutures without closed suction drainage

Study burden and risks

Patients will be informed about the study before inclusion in the outpatient clinic. Informed consent will be obtained in the outpatient clinic a week after patients were initially informed. Postoperative check-ups will be done more frequently. Standard postoperative check-ups are planned at 2 weeks and 3 months. Additional study postoperative check-ups: 6 weeks, 6 months. Therefore, patients will be required to undergo two additional check-ups.
During out patients* visits, patients will hand in a questionnaire scale regarding cosmesis, pain and quality of life.
Patients will be clinically examined as they usually would be.

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

- Older than 18 years

- Female sex
- Indication for mastectomy or modified radical mastectomy

Exclusion criteria

- Patients undergoing breast conserving therapy
- Patients undergoing direct breast reconstruction
- Patients undergoing modified radical mastectomy
- Unable to comprehend implications and extent of study and sign for informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-06-2020
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO

Date:	20-03-2019
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO Date:	17-02-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	30-04-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	12-06-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	29-03-2021
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	25-01-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	18-06-2024
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL68870.096.19