EvaLuating negAtive pressUre wound theRapy in brEast coNserving surgery - the LAUREN pilot study

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The primary objective of this trial is to compare the number of postoperative wound complications in patients with and without negative pressure therapy after breast conserving surgery in the first three months after surgery. Wound complications...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON53621

Source
ToetsingOnline

Brief title
LAUREN

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, mammacarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Vanuit borstcentrum

Intervention

Keyword: breast cancer, Breast conserving surgery, Negative pressure wound therapy

Outcome measures

Primary outcome

Number of patients with postoperative wound complications during the first three months after surgery. Wound complications include:

o clinically significant seroma. This is defined as seroma which: a) compromises wound healing, b) causes significant pain or discomfort or c) is contaminated, and requires intervention (aspiration, surgical debridement).

o surgical site infections requiring oral or intravenous antibiotic treatment or surgical intervention(s).

o wound dehiscence as defined by the World Union of Wound Healing Societies: separation of the margins of a closed surgical incision that has been made in skin, with or without exposure or protrusion of underlying tissue, organs or implants. Separation may occur at single or multiple regions, or involve the full length of the incision and may affect some or all tissue layers.

o wound necrosis requiring surgical intervention(s).

o hematoma requiring surgical intervention(s).

Secondary outcome

- Pain scores during NPWT. This will be assessed using a visual analogue scale (VAS) ranging from 0-10.

- Burden for patients, which will be measured in two ways: EQ-5D-5L questionnaire and patient interviews in the first 20 patients

- Number of unplanned outpatient clinic visits or phone calls.

- Number of re-interventions.

Study description

Background summary

Negative pressure wound therapy (NPWT) could improve surgical outcomes and reduce complications like SSI, wound dehiscence and seroma in closed surgical wounds. Complication rate after breast conserving surgery for breast cancer is 2-17%, surgical site infections (SSI) being the most common. To date, NPWT was not evaluated in patients undergoing breast conserving surgery without direct reconstruction. Therefore, in this trial, the aim is to evaluate the feasibility of NPWT after breast conserving surgery and its effects on postoperative complications.

Study objective

The primary objective of this trial is to compare the number of postoperative wound complications in patients with and without negative pressure therapy after breast conserving surgery in the first three months after surgery. Wound complications include clinical significant seroma, surgical site infections, wound dehiscence or wound necrosis.

Secondary, in this trial the following secondary objectives will be assessed:
1. Pain scores
2. Burden for patients
3. Number of unplanned outpatient clinic visits or phone calls
4. Number of re-interventions

Study design

A prospective cohort of 150 patients will be compared to a retrospective cohort of 150 patients.

Intervention

Negative pressure wound therapy

Study burden and risks

When participating in this study, patients will need to pay at least one extra visit to the hospital, possibly two if this cannot be combined with the standard postoperative visits. In addition, patients will need to have a device

with them for 14 days after surgery. This device is connected to the wound dressing. All wound dressings may cause irritation or an allergic reaction. This risk is not higher than when receiving standard wound dressing, but it is something to take into consideration.
Patients participating in this study may benefit from NPWT regarding the postoperative complication rate.

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

- Eighteen years or older.
- Female sex.
- Indication for breast conserving surgery, with or without sentinel lymph node

biopsy

Exclusion criteria

- Undergoing mastectomy or modified radical mastectomy.
- Undergoing direct breast reconstruction.
- Patients with a pacemaker, ICD or other medical device in the proximity of the wound area, due to the magnet in the PICO® device.
- Unable to comprehend implications and extent of the study and/or unable to sign for informed consent.
- Participation in another breast cancer surgery related clinical trial.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-06-2023
Enrollment:	300
Type:	Actual

Medical products/devices used

Generic name:	PICO14 (negative pressure wound therapy)
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	25-07-2022
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	19-04-2023
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	NL81779.096.22