Evaluating Hemopatch in reducing seroma related complications following axillary lymph node dissection: a pilot study

Published: 06-11-2019
Last updated: 10-04-2024

To evaluate if the use of Hemopatch in axillary lymph node dissection shows potential in reducing clinically significant seroma and seroma related complications, which might serve as a basis for a randomized controlled trial.

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

Summary

ID

NL-OMON48337

Source
ToetsingOnline

Brief title
HEIDI

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

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: axillary lymph node dissection, seroma

Outcome measures

Primary outcome

To assess

1. Proportion of patients treated with Hemopatch who develop clinically

significant seroma during the first three post-operative months. Clinically

significant seroma defined as:

a. Wound healing is at risk due to seroma (wound break down, seroma

leakage, necrosis) and possibly operative debriding of the wound or use of

vacuum assisted wound therapy is necessary.

b. The presence of discomfort or pain caused by large amounts of

seroma, characterised by tenseness of the skin and aspiration is necessary

c. The presence of contaminated/ infected seroma, and aspiration is

necessary to treat infection. All patients that undergo seroma aspiration due

to infection will also be treated with a one week course of Augmentin 625 mg 3

times daily.

d. Seroma for which incision and drainage is necessary to treat abscess

or

infection.

Secondary outcome

To assess

1. 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 three postoperative months.

2. The number of outpatient department visits, measured during the first three months postoperative.

3. Number of days before removal of axillary drainage and axillary drainage output. According to current guidelines the drain is always removed no later than five days, earlier if drain output is < 50 ml/ 24 hours

Study description

Background summary

Sentinel lymph node biopsy has reduced the number of patients needing to undergo axillary lymph node dissection (ALND). However, axillary lymph node dissection is part of curative therapy for a large group of patients with advanced invasive breast cancers and melanoma. Seroma may cause symptomatic discomfort requiring needle aspiration and is often associated with infection, wound dehiscence, skin necrosis, persistant fibrotic encapsulated seromas and may even delay adjuvant therapies. Therefore, extensive research in finding the best technique in reducing seroma is needed.
Substances intended to seal small blood vessels by triggering collagen and fibrinogen synthesis supporting surgical hemostasis, are assumed to be able to contribute to sealing of these lymphatic vessels. Contradicting results were found in the effect of several fibrin-glue coated collagen patches and fibrin glue.
This pilot study is intended to assess the value of a haemostatic sealant (Hemopatch), a pad of collagen derived from bovine dermis, coated with NHS-PEG (pentaerythritol polyethylene glycol ether tetra-succinimidyl glutarate), in reducing seroma related complications after ALND with the advantage that this sealant is pliable and flexible.

Study objective

To evaluate if the use of Hemopatch in axillary lymph node dissection shows

potential in reducing clinically significant seroma and seroma related complications, which might serve as a basis for a randomized controlled trial.

Study design

A prospective cohort will be compared to a historical control group. Eighteen consecutive patients will undergo axillary lymph node dissection and after completion of lympheadenectomy, Hemopatch will be applied to the axillary surgical field. These results will be compared to the results of a historical control group consisting of 46 patients who have undergone ALND without the Hemopatch between January 2014 and December 2018.
Follow-up will be conducted for three months postoperatively.

Intervention

Application of Hemopatch after standard axillary lymph node dissection.

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 one week and three months. Additional study postoperative check-up will be performed at six weeks. Therefore, patients will be required to undergo one additional check-up. During out patients* visits, the wound will be evaluated. Application of the Hemopatch is expected to reduce clinically significant seroma after ALND. The only potential risk for the patient is that the Hemopatch is ineffective.

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

- Male and female patients of 18 years or older.
- Patients with melanoma and indication for axillary lymph node dissection.
- Patients with breast cancer and indication for breast conserving therapy and axillary lymph node dissection
- Patients with an indication for secondary axillary lymph node dissection.

Exclusion criteria

- Patients with breast cancer who have an indication for modified radical mastectomy.
- Unable to comprehend implications and extent of study and sign for informed consent
- Pregnant women
- Patients included in another breast 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:	Recruitment stopped
Start date (anticipated):	16-06-2020
Enrollment:	64
Type:	Actual

Ethics review

Approved WMO Date:	06-11-2019
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	20-05-2020
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	NL71255.096.19