

# Comparing surgical techniques for removal of the groin lymph nodes in the treatment of vulvar cancer

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| <b>Submission date</b><br>21/12/2018   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>29/01/2019 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>04/09/2020       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

In around half of the women with vulvar cancer surgical removal of the lymph nodes in the groin (inguinofemoral lymphadenectomy) is part of the treatment. Unfortunately, up to 85% of these patients suffer from postoperative complications. The most frequent complications are: spontaneous wound rupture along the surgical incision (wound dehiscence), infection of the wound (wound infection) and the collection of lymphatic fluid in the groin (lymphocele). These complications might lead to additional treatment or readmission to the hospital. A recent prospective study of our study group showed that 47-66% of the patients needed treatment for one of the mentioned complications. In addition, 27-32% of the patients needed to be readmitted because of a complication. These complications are both a high burden for the patient and the treating clinician and a significant increase in the costs of healthcare. For these reasons, there is an urgent need for other surgical techniques to reduce the complications after surgical removal of the groin lymph nodes.

The use of a LigaSure sealing device might reduce the complications after surgical removal of the groin lymph nodes; during surgical removal of the groin lymph nodes, the lymph vessels are damaged in order to remove the lymph nodes. By sealing the lymph vessels instead of cutting, there may be less lymph fluid leakage after surgery. This may result in a reduction in the complications.

The aim of this study is to compare complications of the surgical removal of the groin lymph nodes using two different surgical methods in women with vulvar cancer.

### Who can participate?

Women aged  $\geq 18$  years diagnosed with vulvar cancer, type squamous cell carcinoma, undergoing surgical removal of the lymph nodes in both groins (inguinofemoral lymphadenectomy).

### What does the study involve?

The inguinofemoral lymphadenectomy will be the standard procedure for both groins. During this surgical procedure, LigaSure will be used for one groin and the conventional method (sharp or diathermia) for the other groin. It will be randomly assigned for which groin LigaSure will be

used. By performing both surgical techniques in the same patient, confounding patient characteristics are equal and therefore the outcomes for both groins within a patient can be compared. After surgery, the standard postoperative care will be given, and the patient will receive standard follow-up care by the gynecologic oncologist.

What are the possible benefits and risks of participating?

The use of LigaSure for (lymph)vessel sealing is widely accepted and used during surgery for different surgical procedures. The advantages (reducing short-term complications, lymphoceles, volume drained, duration of drainage and duration of hospital stay) and safety of the LigaSure sealing device has been reported in many published studies. Participation in this study therefore does not pose any risk. The results from this study may benefit the women with vulvar cancer undergoing surgical removal of the lymph nodes in the groin (inguinofemoral lymphadenectomy).

Where is the study run from?

This study will be performed in two centers in the Netherlands: the Radboud university medical center and the University Medical Center Groningen.

When is the study starting and how long is it expected to run for?

The study started on September 30, 2017 and was completed on November 22, 2018.

Who is funding the study?

No funding.

Who is the main contact?

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

NL62326.091.17

# Study information

## Scientific Title

Ligasure versus conventional surgery for inguinofemoral lymphadenectomy in vulval cancer patients: a multi-centre randomised controlled trial

## Acronym

MAMBO-IC

## Study objectives

By sealing the lymph vessels, there may be less lymph fluid leakage after surgery which may result in a reduction in the postoperative morbidity, such as wound infection, lymphocele and/or wound dehiscence. We hypothesize that the use of LigaSure for IFL results in a reduction of postoperative morbidity in vulvar cancer patients.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Medical Ethical Committee region Arnhem-Nijmegen, the Netherlands, 14/09/2017, ref. 2017-3384

## Study design

Interventional, multicenter randomized controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a participant information sheet

## Health condition(s) or problem(s) studied

Vulval cancer

## Interventions

The inguofemoral lymphadenectomy will be the standard procedure for both groins. For the intervention groin, the LigaSure device will be used to perform this surgical procedure and for the other groin, the conventional method (scalpel and/or electrocautery) will be used.

The IFL will contain resection of superficial lymph nodes as well as deep femoral nodes. For the resection of inguinal lymph nodes, the fatty tissue beneath the subcutaneous tissue down to the fascia lata will be removed. The saphenous vein will be spared when possible. The femoral lymphadenectomy will be performed by splitting the fascia lata, and then resecting the node bearing fatty tissue medial to the femoral vessels within the opening of the fossa ovalis. The lateral part of the fascia lata will be spared and no Sartorius transposition will be performed. The wound will be closed in two layers and the skin will be closed with staples/stitches/intra cutaneous.

#### Randomization process

Patients were randomized to the intervention (LigaSure) for either the left or right groin. We used a variable block randomization method, with a block division of 2, 4 using Castor EDC.

#### Follow-up

During the regular visits at the outpatient clinic two weeks after removal of the drains and eight weeks after surgery, the groins will be examined by a gynecologist or special wound care nurse and the incidence of any short term complication (wound breakdown and/or wound infection and /or lymphocele) will be assessed. All incidents and/or complications occurring within these 8 weeks will be documented.

#### Intervention Type

Procedure/Surgery

#### Primary outcome measure

The incidence of any short term complication (wound breakdown and/or wound infection and/or lymphocele) will be measured within 8 weeks after inguofemoral lymphadenectomy.

#### Secondary outcome measures

1. Surgeon experience using LigaSure will be measured using a questionnaire containing SURG-TLX.
2. Patient experience (including the maximum and minimum postoperative pain measured by a visual analogue score (VAS) and restriction of daily activities scored between 0 (no restrictions) and 10 (completely restricted)) will be measured using a questionnaire by telephone between 6 and 8 weeks after surgery.
3. Operating time for inguofemoral lymphadenectomy will be measured in minutes from incision to end of closure for each groin separately.
4. The volume drained per day in millilitres per 24 hours per groin will be measured during the period when the drain is in situ.
5. The duration of drainage in days.
6. The duration of hospital stay in days.
7. The frequency and duration of re-admission during the follow-up period of 8 weeks.
8. The percentage of primary wound healing 8 weeks after inguofemoral lymphadenectomy.
9. The days wound care (number of days paid care is necessary) (intra- and extramural) is needed per groin during follow up.
10. The need and nature of intervention following any short term complication per groin.

#### Overall study start date

21/01/2017

**Completion date**

22/11/2018

## Eligibility

**Key inclusion criteria**

1. Female sex
2. Age  $\geq$  18 years
3. Squamous cell carcinoma of the vulva with indication for bilateral inguino-femoral lymphadenectomy by separate groin incisions (also after SN procedure)
4. Able to visit the outpatient clinic

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

20

**Total final enrolment**

20

**Key exclusion criteria**

1. Previous radiotherapy to vulva, groins and/or pelvis
2. Previous pelvic lymphadenectomy
3. Any histology other than squamous cell carcinoma
4. Patient with indication for inguino-femoral lymphadenectomy with 'en bloc' approach

**Date of first enrolment**

15/09/2017

**Date of final enrolment**

22/11/2018

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**  
**Radboud university medical center**  
Geert Grooteplein Zuid 10  
Nijmegen  
Netherlands  
6525 GA

**Study participating centre**  
**Universitair Medisch Centrum Groningen**  
Hanzeplein 1  
Groningen  
Netherlands  
9713 GZ

## **Sponsor information**

**Organisation**  
Radboud university medical center

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**Sponsor type**  
Hospital/treatment centre

**Website**  
[www.radboudumc.nl](http://www.radboudumc.nl)

**ROR**  
<https://ror.org/05wg1m734>

## **Funder(s)**

**Funder type**  
Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

30/06/2019

**Individual participant data (IPD) sharing plan**

The data sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/12/2020   | 04/09/2020 | Yes            | No              |