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

Submission date
21/12/2018

Recruitment status
No longer recruiting

Registration date
29/01/2019

Overall study status
Completed

Last Edited
04/09/2020

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 ≥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 gyneacologic 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

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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 inguinofemoral 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 inguinofemoral 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 inguinofemoral lymphadenectomy will be measured in minutes from incision to end of closure for each groin separately.
4. The volume drained per day in mililitres 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 inguinofemoral 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 ≥ 18 years
3. Squamous cell carcinoma of the vulva with indication for bilateral inguinofemoral 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 inguinofemoral 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
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Study participating centre
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
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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?
Results article	results	01/12/2020	04/09/2020	Yes	No