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Understanding the risks and complications of surgery for penile cancer near the groin area

Submission date 22/11/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 01/12/2025	**Overall study status** Ongoing	
Last Edited 21/01/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Penile cancer is a rare disease that mostly affects older men. The main risk factors are Human Papilloma Virus (HPV), chronic inflammation, penile intraepithelial neoplasia and smoking. Penile cancer can spread to lymph nodes in the groin. Patients with penile cancer spread to the groin are treated with inguinal lymph node dissection. A drain is put in the groin to drain excess fluid from the groin after surgery. The drain is removed when there is less than 50 ml in drain per day in two consecutive days.

Inguinal lymph node dissection puts the patient at risk of complications such as lymphorrea, seroma, infection, bleeding and lymphocele. The aim of this study will investigate if the time with drain and risk of complications can be reduced using a vessel sealing device called LigaSure Exact Dissector(LS) during surgery compared to standard of care (SOC).

Who can participate?
Penile cancer patients that are operated with inguinal lymph node dissection in Sweden, Norway or Denmark can participate in the study.

What does the study involve?
The study participants are randomized to either LS och SOC. Information from the surgery and during follow up of 10-14 months are collected using forms and volume measurements of scrotum and lower limbs.

What are the possible benefits and risks of participating?
The advantage of participating in the trial is that, if we can demonstrate that the LigaSure Exact Dissector reduces complications compared to the surgical technique we use today, future patients will benefit from your participation. For you personally, there is also an advantage in taking part in the study, as you will be thoroughly followed up regarding any potential complications.
The risk associated with participating in the trial is that you may experience an intrusion of privacy because medical record information concerning your condition, the surgery, and any complications will be collected. The collected study data will be handled in a coded /pseudonymised manner.

Where is the study run from?
The study is run from Skåne University hospital in Malmö Sweden.

When is the study starting and how long is it expected to run for?
The study starts in January 2026 and will run for 5 years.

Who is funding the study?
This clinical trial is funded by the Gösta Jönssons foundation, the Hillevi Fries foundation, The foundation for urological research and Region Skåne (USVE).

Who is the main contact?
Axel Gerdtsson, PhD, MD, Dept of urology, Skåne university hospital, Malmö, Sweden is the main contact.
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Contact information

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Principal investigator, Public, Scientific

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CIV-ID
CIV-24-09-049274

Study information

Scientific Title
Complications in inguinal lymph node dissection for patients with penile cancer

Acronym
COMPLY

Study objectives

Primary objective: To assess if time (days) until inguinal drain removal is shorter with LS compared to SOC.
Secondary objectives:
1. To assess whether LS (ligasure technique) reduces surgical site complications compared to SOC (standard of care).
2. To measure the complication rate using the Clavien-Dindo classification up to 90 days after surgery.
3. To determine if LS is superior to SOC in terms of shorter operating time and lower total drain volume.
4. To investigate whether LS is superior to SOC in reducing the proportion of patients with lower limb lymphedema at 3–5 months and 10–14 months after ILND (inguinal lymph node dissection).
5. To assess whether LS is superior to SOC in reducing the proportion of patients with scrotal lymphedema at 3–5 months and 10–14 months after ILND.
6. To quantify and evaluate scrotal and lower limb lymphedema using CT scans.
7. To assess whether scrotal volume measurement with a caliper gauge and lower limb volume with the V8 method are equivalent to measurements obtained from CT scans.
8. To evaluate whether LS affects health-related quality of life (HrQoL) less than SOC at 3–5 months and 10–14 months after ILND compared to baseline.
9. To determine if LS is cost-effective by calculating the incremental cost-effectiveness ratio (ICER) at 3–5 months and 10–14 months.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/11/2025, Etikprövningsmyndigheten Stockholm avdelning 1 medicin (Box 2110, Uppsala, 75002, Sweden; +46 104750800; registrator@etikprovning.se), ref: 2025-07419-01

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Basic science, Device feasibility, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Penile cancer patients operated with inguinal lymph node dissection.

Interventions
Subjects will be randomly assigned 1:1 to either the control group, that will undergo the standard of care (SOC) or the intervention group that will be operated with LigaSure Exact Dissector (LS). The study subjects will undergo inguinal lymph node dissection according to the randomization. Preservation of the fascia lata and saphenous vein will be done when possible. The wound will be closed according to local guidelines.

The following situations are accepted for subjects randomized to LS, ligature/clips on vessels exceeding 7mm, dissection of the saphenous vein or femoral artery using bipolar scissor, electrocautery of bleeding not suitable or unavailable for the LS device.

The LS will be compared to standard of care “SOC”, which comprises all methods for vessel sealing except LS. The method/s of use of in SOC is up to the surgeon’s preference.

The randomization process will be in RedCAP. The inclusion/exclusion criteria for the study must be answered in order to get the the randomization result. The patients are stratified on the study site. This means that around 50% of the patients at each site will be randomized to intervention and 50% to SOC. Every site has 4 sealed envelopes to use for randomization If the RedCAP can't be reached.

Intervention Type
Drug/Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
LigaSure Exact Dissector

Primary outcome(s)
1. Time from inguinal lymph node dissection to drain removal (less than 50 ml of drain fluid, in two consecutive days) measured using patient records at up to 60 days

2. Surgical site complication rate ,wound infection, lymphocele, lower limb lymphedema on the same side as the ILND performed measured using chart record at up to 90 days

3. The 90-day complication rate measured using chart record at up to 90 days

4. Operating time measured using minutes at day 1

5. Total drain volume measured using ml at up to 60 days

6. Volume measurement of lower limbs measured using V8-method and CT-scan at 0, 3-5 and 10-14 months.

7. Scrotal volume measured using caliper gauge and CT-scan at 0, 3-5 and 10-14 months

8. Total HrQoL-score measured using Lymph edema quality of life (LYMQOL) at 0, 3-5 and 10-14 months

9. Calculation of ICER measured using EQ-5D-5L at 0, 3-5 and 10-14 months.

10. Lymphedema measured using Increment of 10% in excess volume (swollen limb/scrotum volume-normal limb/scrotum volume) of lower limbs or scrotum compared to baseline on either: -CT-scan of lower limb or scrotum. -scrotal volume measured with caliper gauge -lower limb volume measurement using V8 method -received treatment for lymphedema (compression stockings) at up to 14 months

Key secondary outcome(s))

Completion date
12/05/2031

Eligibility

Key inclusion criteria
1. Diagnosis of penile cancer
2. Scheduled to be operated with inguinal lymph node dissection
3. Able and willing to fill in forms electronically or in paper form at the clinic with the assistance of the study nurse
4. Written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
Male

Total final enrolment
0

Key exclusion criteria
1. <18 years
2. Unable to understand the subject information according to the investigator’s judgement
3. Pacemaker or other implanted devices as medically judged by the Investigator NOT to be applicable with LigaSure Exact Dissector use

Date of first enrolment
21/01/2026

Date of final enrolment
12/01/2030

Locations

Countries of recruitment
Denmark

Norway

Sweden

Sponsor information

Organisation
Region Skåne

ROR
https://ror.org/03sawy356

Funder(s)

Funder type

Funder Name
Gösta Jönssons foundation

Funder Name
Hillevi Fries foundation

Funder Name
The foundation for urological research and Region Skåne (USVE)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	12/09/2025	24/11/2025	No	Yes
Protocol file	version 1	25/09/2025	24/11/2025	No	No
Statistical Analysis Plan	version 1	25/09/2025	24/11/2025	No	No