

Evaluation of lymph node surgery in patients with upper urinary tract carcinoma

Submission date 09/09/2015	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/10/2015	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/04/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The most common type of bladder cancer is transitional cell bladder cancer (TCC), also known as urothelial carcinoma. This type of bladder cancer starts in the cells that line the inside of the bladder (transitional cells), which are designed to expand when the bladder is full and contract when it is empty. These same cells also line the tubes which carry urine from the kidney to the bladder (ureter) and out of the body (urethra). Cancers of the upper urinary tract are most common in the renal pelvis (the part of the kidney that connects to the ureters) or the renal calyces (the part of the kidney where urine is collected). The main treatment for this is an operation called a nephroureterectomy, where the kidney and renal pelvis is removed. In some cases of urothelial carcinoma, the cancerous cells can spread around the body (metastases). In order to find out the extent of this an operation called a retroperitoneal lymphadenectomy is performed, in which the lymph nodes (swellings which produce white blood cells) are removed and examined. There is little evidence of nephroureterectomies and retroperitoneal lymphadenectomies being carried out at the same time. The aim of this study is to find out where lymph node metastases are located in urothelial carcinomas of the upper urinary tract.

Who can participate?

Adults with advanced urothelial carcinoma in Sweden.

What does the study involve?

At the time of surgery, the location of lymph node metastases is recorded in all patients. Over a two year follow up period, imaging is completed in order to find out if the lymph node metastases have returned. For 90 days after surgery, patients attend follow up appointments so that any surgical complications from the surgery can be recorded.

What are the possible benefits and risks of participating?

There are no specific benefits of participating in the study. There are no risks of participating other than the usual risks which accompany major surgery.

Where is the study run from?

Skåne University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
January 2015 to January 2028

Who is funding the study?
Lund University (Sweden)

Who is the main contact?
Dr Fredrik Liedberg
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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
N/A

Study information

Scientific Title
Lymphadenectomy in urothelial carcinoma in the renal pelvis/calices (LURP-study)

Acronym
LURP-study

Study objectives

This study aims to find where lymph node metastases are located in urothelial carcinomas of the upper urinary tract.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics Board of Lund University, 09/06/2013, ref: 2013/321

Study design

Single-centre observational case series

Primary study design

Observational

Secondary study design

Case series

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Urothelial carcinoma of the upper urinary tract

Interventions

At the time the retroperitoneal lymphadenectomy is performed on the participants, the location of the lymph node metastases is recorded. The participants are then monitored for 90 days post-surgery for post-surgical complications. After two years, using radiological methods, the location of any further metastases are recorded.

Intervention Type

Procedure/Surgery

Primary outcome measure

Location of lymph node metastasis measured at retroperitoneal lymphadenectomy during follow up if the patients suffer from lymph node recurrence, within a two year period.

Secondary outcome measures

Post surgical complications are monitored throughout 90 days after surgery, by examining patient charts. After 90 days, a Clavien score between 0 and 5 is determined.

Overall study start date

01/01/2014

Completion date

01/01/2028

Eligibility

Key inclusion criteria

1. Aged 18 years or over
2. Locally advanced high grade urothelial carcinoma in the renal pelvis or upper 2/3 of the ureter (Clinical stage > T1)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

Clinical suspicion of non-muscle invasive UUTUC

Date of first enrolment

01/01/2014

Date of final enrolment

01/03/2027

Locations

Countries of recruitment

Norway

Sweden

Study participating centre

Skåne University Hospital

Södra Förstadsgatan 101

Malmö
Sweden
20502

Study participating centre
St Olavs University Hospital of Trondheim
Department of Urology
Norway
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Sponsor information

Organisation
Lund University

Sponsor details
Institute Translational Medicine
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205 02

Sponsor type
University/education

Website
<http://www.lunduniversity.lu.se/>

ROR
<https://ror.org/012a77v79>

Funder(s)

Funder type
University/education

Funder Name
Lund University

Results and Publications

Publication and dissemination plan

Publication in a peer reviewed journal.

Intention to publish date

01/01/2030

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