

Health related quality of life after radical cystectomy

Submission date 09/09/2015	Recruitment status Recruiting	<input checked="" 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

Bladder cancer refers to a condition where a tumour grows in the lining of the bladder which can then spread to other tissues in the body. The most common symptom is blood in the urine. Transurethral resection for bladder cancer, a surgery that involves removing the cancer cells from the bladder, is the most common urologic cancer operation today. In cases where transurethral resection shows that the tumour has spread into the surrounding muscle, the standard treatment is radical cystectomy (removal of the bladder, surrounding lymph nodes, part of the urethra and other nearby organs that may have cancer cells). Patients considered well enough may have chemotherapy before surgery to increase the chance of a cure. To study the outcome after a radical cystectomy, the health-related quality of life (HRQoL) is a measure that takes both the impact of the disease and treatment-related side effects into account. HRQoL is rarely measured for bladder cancer patients after treatment due to a lack of bladder cancer-specific validated questionnaires and its various treatments. FACT (Functional Assessment of Cancer Therapy Scale) is designed to measure the physical, social, emotional and functional wellbeing of patients after treatment. It was originally developed for use in different kinds of gastric surgery and has later been validated for other cancers. For patients with bladder cancer treated with radical cystectomy, various questionnaires including EORTC-QLQ30-BLM30, FACT-VCI (Vanderbilt Cystectomy Index) and BCI (Bladder Cancer Index) have all been validated for use. Of these questionnaires, the FACT-VCI is based on the FACT, with diversion-related questions (i.e. questions about rerouting urine flow away from its normal path) added, making the questionnaire particularly useful in the setting before (FACT-G) and after (FACT-VCI) radical cystectomy. The aim of this study is to investigate health-related quality of life (HRQoL) using these questionnaires before and after radical cystectomy in relation to whether they have had chemotherapy, type of urinary diversion and complications after surgery.

Who can participate?

Patients treated with primary radical cystectomy in Sweden.

What does the study involve?

Participants complete the questionnaire with FACT-G before surgery and FACT-VCI after

surgery. Comparisons in HRQoL are then made taking into account whether they have had chemotherapy, type of urinary diversion and whether or not they have any complications within 90 days of surgery.

What are the possible benefits and risks of participating?

The benefits for participants are a more thorough registration of health changes after radical surgery. There are no risks.

Where is the study run from?

Skåne University Hospital, Lund University (Sweden)

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

January 2016 to January 2028

Who is funding the study?

MAS Cancer Foundation (Sweden)

Who is the main contact?

Dr Fredrik Liedberg

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Patient Reported Outcome Measures after radical cystectomy

Acronym

PROM

Study objectives

The aim of this study is to investigate health related quality of life (HRQoL) before and after radical cystectomy in relation to neoadjuvant chemotherapy, type of urinary diversion and complications after surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Lund University, ref: 2014/832

Study design

Observational cohort

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Bladder cancer treated with radical cystectomy

Interventions

Participants are asked to fill in two questionnaires, tFACT-G and FACT-VCI to assess their HRQoL after radical cystectomy.

Intervention Type

Other

Primary outcome(s)

HRQoL at 12 months after radical cystectomy for bladder cancer, assessed with tFACT-G and FACT-VCI.

Key secondary outcome(s)

The secondary outcome measures are the HRQoL items functional wellbeing, social wellbeing, emotional wellbeing and physical wellbeing. These are measured 12 months after surgery. The method used is the FACT-VCI questionnaire, as for the primary outcome measures.

Completion date

01/01/2028

Eligibility

Key inclusion criteria

Patients with bladder cancer scheduled to have a radical cystectomy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Does not give consent

Date of first enrolment

01/01/2016

Date of final enrolment

01/03/2027

Locations

Countries of recruitment

Sweden

Study participating centre

Skåne University Hospital, Lund University

Malmö

Sweden

205 02 Malmö

Sponsor information

Organisation

Inst Translational Medicine, Lund University

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

MAS Cancer Foundation (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available