

# Health related quality of life after radical cystectomy

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<b>Registration date</b> 07/10/2015	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/04/2025	<b>Condition category</b> 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

Dr Fredrik Liedberg

### Contact details

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Quality of life

**Participant information sheet**

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

**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 measure**

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

## Secondary outcome measures

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.

## Overall study start date

01/01/2016

## Completion date

01/01/2028

# Eligibility

## Key inclusion criteria

Patients with bladder cancer scheduled to have a radical cystectomy

## Participant type(s)

Patient

## Age group

Adult

## Sex

Both

## Target number of participants

900

## 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

## Sponsor details

205 02

Malmö

Sweden

205 02

## Sponsor type

University/education

## ROR

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

# Funder(s)

## Funder type

Research organisation

## Funder Name

MAS Cancer Foundation (Sweden)

# Results and Publications

## Publication and dissemination plan

The study will be published in a peer reviewed journal in 2024.

## Intention to publish date

01/01/2030

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not expected to be made available