

Investigation of continence, sexual- and bowel function after radical surgery for bladder cancer

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

Plain English summary of protocol

Background and study aims

Bladder cancer is one of the most common types of cancer worldwide. If the cancer has spread particularly aggressively or keeps coming back after initial treatment, a radical cystectomy may be required. A radical cystectomy is an operation where the entire bladder is removed, as well as nearby organs that may contain cancer cells, such as the prostate and vas deferens (tubes that transport sperm) in men, and the uterus and ovaries in women. Although total removal of the bladder is an effective treatment against the cancer, patients often experience long-term side effects from the surgery. One of the most pronounced after-effects are problems with functional problems, namely sexual problems and urinary incontinence. Another common problem following a radical cystectomy is difficulties with bowel movements, such as difficulty passing stools or needing to go urgently. The aim of this study is to look at defecation (rectal function) in patients before and after their radical cystectomy surgery.

Who can participate?

Adults suffering from bladder cancer, with a planned radical cystectomy.

What does the study involve?

Before the planned surgery, participants are asked to complete questionnaires regarding their sexual function and continence. Additionally, pressure measurements in the rectum are taken so that rectal function can be determined. Twelve months after the patients have had their radical cystectomy, the questionnaires and function tests are repeated to find out whether the results have changed.

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 radical cystectomy.

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 March 2028

Who is funding the study?
MAS Cancer (Sweden)

Who is the main contact?
Dr Fredrik Liedberg
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Functional outcomes after radical cystectomy – with emphasis on continence, sexual and rectal function – a prospective study

Acronym
FORC-study

Study objectives
Rectal function after anterior exenteration correlates with physiologic findings post-operatively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Board of Lund University, 20/03/2014, ref: 2014/163

Primary study design
Observational

Study design

Prospective investigational

Study type(s)

Other

Health condition(s) or problem(s) studied

Bladder cancer treated with radical cystectomy

Interventions

Before the radical cystectomy procedure, patients complete a number of questionnaires concerning their sexual function and faecal continence. Additionally, rectal function is measured using manuvolumetry at this time. 12 months after the surgery, the questionnaires and rectal function tests are repeated.

Intervention Type

Other

Primary outcome(s)

1. Decline in sexual function measured using IIEF-5 questionnaire (erectile dysfunction) for male participants and FSFI (female sexual dysfunction) questionnaire for female participants before surgery (baseline) and 12 months post-operatively
2. Incontinence measured using the St Mark's questionnaire (faecal incontinence) before surgery (baseline) and 12 months post-operatively
3. Rectal function is measured by manuvolumetry is measured by maximum closure pressure (MACP) and resting anal sphincter pressure (RASP) before surgery (baseline) and 12 months post-operatively

Key secondary outcome(s)

Rectal function assessed preoperatively and postoperatively after radical cystectomy using transrectal manuvolumetry and transrectal ultrasound, before surgery (baseline) and 12 months post-operatively.

Completion date

01/03/2028

Eligibility

Key inclusion criteria

1. Aged 18 years or over
2. Planned radical cystectomy for bladder cancer

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Previous pelvic radiation

Date of first enrolment

01/01/2015

Date of final enrolment

01/03/2027

Locations**Countries of recruitment**

Sweden

Study participating centre

Skåne University Hospital

Södra Förstadsgatan 101

Lund University

Malmö

Sweden

201 05

Sponsor information**Organisation**

Lund University

ROR

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

Funder(s)**Funder type**

Research organisation

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other