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	Overall study status	Statistical analysis plan
07/10/2015	Ongoing	Results
Last Edited	Condition category	Individual participant data
09/04/2025	Cancer	[X] 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 fredrik.liedberg@skane.se

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

N/A

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

Study design

Prospective investigational

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Other

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

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 measure

- 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. Inontinence 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

Secondary outcome measures

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

Overall study start date

01/01/2015

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

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

Sponsor details

Institute Translational Medicine Jan Waldenströms gata 35 Malmö Sweden 20502

Sponsor type

University/education

Website

http://www.lunduniversity.lu.se/

ROR

https://ror.org/012a77v79

Funder(s)

Funder type

Research organisation

Funder Name

MAS Cancer

Results and Publications

Publication and dissemination plan

A publication is expected one year after study completion.

Added 26/07/2019: A subgroup analysis and first publication will be submitted beginning 2020.

Intention to publish date

01/01/2027

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