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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 [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
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Contact information

Type(s)
Scientific

Contact name
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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
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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