

Randomized comparison of oophorectomy or not in conjunction with radical cystectomy in women

Submission date 18/04/2017	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/05/2017	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/01/2025	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 is where a tumour develops in the bladder lining. Patients who have high-risk early bladder cancer, invasive bladder cancer or locally advanced bladder cancer may have to have their bladder removed (radical cystectomy). In women, sometimes the ovaries may also need to be removed (oophorectomy). There are at present no studies on whether oophorectomy should be performed with radical cystectomy as treatment for muscle-invasive bladder cancer in women. Information is also lacking regarding the effects on hormone levels and sexual function. This study aims to assess the hormone levels and sexual function of women undergoing radical cystectomy with or without oophorectomy for bladder cancer.

Who can participate?

Women aged 18-85 undergoing radical cystectomy for bladder cancer

What does the study involve?

Participants are randomly allocated to undergo radical cystectomy with either no oophorectomy, removal of one ovary or removal of both ovaries. Sexual function and blood hormone levels are assessed at the start of the study and 12 and 52 weeks after the operation.

What are the possible benefits and risks of participating?

Participants allocated to no oophorectomy may benefit from better hormonal, sexual and general function after surgery. There are no risks in participating in this study.

Where is the study run from?

Skåne University Hospital (Sweden)

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

April 2017 to December 2027

Who is funding the study?

Hillevi Fries Foundation (Sweden)

Who is the main contact?
Prof Fredrik Liedberg

Contact information

Type(s)
Principal investigator

Contact name
Prof Fredrik Liedberg

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Additional identifiers

Protocol serial number
1/2017

Study information

Scientific Title
Impact of oophorectomy at cystectomy for urinary bladder cancer on female hormonal status and sexual function: Randomized study on Oophorectomy at Cystectomy (ROC study)

Acronym
ROC

Study objectives
Preservation of ovarian tissue increases sexual function and improves hormonal status after radical cystectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethical Review Board in Lund, 14/02/2017, ref: 2016/1036 and 2017/2

Study design

Prospective randomised study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bladder cancer treated with radical cystectomy

Interventions

Patients undergoing radical cystectomy will be randomized using closed envelopes to undergo either:

1. No oophorectomy
2. Excision of one ovary
3. Excision of both ovaries

Oophorectomy will be performed by standard surgical methods, including ligation of parametrium with Ligasure when preserving the one or two ovaries. Follow-up will be 12 months postoperatively according to the protocol, however clinical follow-up will be according to clinical routines.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Sexual function, measured using Female Sexual Function Index (FSFI) score at baseline, 12 and 52 weeks postoperatively
2. Hormonal status, measured using plasma levels of total testosterone, dihydrotestosterone, SHBG, anti-müllerian-hormone, androstenedione, dehydroepiandrosterone sulphate, progesterone, oestradiol (sensitive method for postmenopausal women), LH and FSH, at baseline, 12 and 52 weeks postoperatively

Key secondary outcome(s)

No secondary outcome measures

Completion date

31/12/2027

Eligibility

Key inclusion criteria

1. Women undergoing radical cystectomy
2. Aged 18-85 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

85 years

Sex

Female

Key exclusion criteria

1. Clinical suspicion of tumour involvement of either ovaries
2. Previous radiation of the pelvis
3. Previous cystectomy
4. Previous oophorectomy

Date of first enrolment

18/04/2017

Date of final enrolment

31/12/2026

Locations

Countries of recruitment

Sweden

Study participating centre

Skåne University Hospital

Department of Urology

Malmö

Sweden

SE-205 02

Sponsor information

Organisation

Lund University

ROR

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

Funder(s)

Funder type

Charity

Funder Name

Hillevi Fries Foundation

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to integrity reasons for the participating patients.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes