

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

<b>Submission date</b> 18/04/2017	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/05/2017	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/03/2026	<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 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 2028

### 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

### ORCID ID

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### Contact details

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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**

31/12/2028

# **Eligibility**

## **Key inclusion criteria**

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

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

85 years

**Sex**

Female

**Total final enrolment**

0

**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**

31/12/2027

## **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**

**IPD sharing plan summary**

Not expected to be made available