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

Submission date	Recruitment status	Prospectively registered
18/04/2017	Recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
24/05/2017	Ongoing	☐ Results
Last Edited	Condition category	☐ Individual participant data
24/01/2025	Cancer	[X] 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)

# Contact information

# Type(s)

Principal Investigator

#### Contact name

Prof Fredrik Liedberg

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers 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

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

# Study type(s)

Treatment

## Participant information sheet

No participant information sheet available

# 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 measure

- 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

#### Secondary outcome measures

No secondary outcome measures

# Overall study start date

09/04/2017

# Completion date

31/12/2027

# Eligibility

# Key inclusion criteria

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

# Participant type(s)

**Patient** 

# Age group

Adult

# Lower age limit

18 Years

#### Upper age limit

85 Years

#### Sex

Female

# Target number of participants

360 female patients

# 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** 

## Sponsor details

Dept. of Translational Medicine Malmö Sweden 205 02

## Sponsor type

University/education

#### **ROR**

https://ror.org/012a77v79

# Funder(s)

# Funder type

Charity

#### **Funder Name**

Hillevi Fries Foundation

# **Results and Publications**

# Publication and dissemination plan

The study will be published in a urologic journal after closure.

# Intention to publish date

31/12/2027

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