ISRCTN18217210 https://doi.org/10.1186/ISRCTN18217210

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

Submission date
18/04/2017

Recruitment status
Recruiting

Registration date
24/05/2017

Overall study status
Ongoing

Last Edited
24/01/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[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)

Who is the main contact?
Prof Fredrik Liedberg

Contact information

Type(s)
Principal Investigator

Contact name
Prof Fredrik Liedberg

ORCID ID
http://orcid.org/0000-0001-8193-0370

Contact details
Dept. of Urology
Skåne University Hospital
Jan Waldenströmsgata 5
Malmö
Sweden
SE-205 02
+46 40331000
fredrik.liedberg@med.lu.se

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