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Robotic-assisted versus open removal of the bladder in bladder cancer patients

Submission date 01/10/2019	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/11/2019	**Overall study status** Ongoing	
Last Edited 17/12/2024	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

Bladder cancer is one of the most common forms of cancer. For most patients, the bladder cancer is superficial and can be treated locally in the bladder. However, for about one in five patients, cancer invades the bladder muscle and for these the most common curative treatment is cystectomy. Cystectomy can be performed either as open surgery, with a longer incision in the lower abdomen, or as a robot-assisted laparoscopic procedure. Robot-assisted laparoscopic cystectomy has been developed during the last 15 years and is routinely performed at some centres around the world. However, it is not entirely certain that a laparoscopic cystectomy is as safe as open surgery, or that there are sufficient advantages to offset the higher procedure-related costs. The aim of this study is, therefore, to find out whether robot-assisted laparoscopic cystectomy is oncologically as safe as open cystectomy, whether there is a difference in rates of complications, and if it is cost-effective

Who can participate?

Men and women with urinary bladder cancer planned to undergo cystectomy

What does the study involve?

Participants are randomly allocated to either robot-assisted laparoscopic cystectomy (experimental group) or open cystectomy (control group)

What are the possible benefits and risks of participating?

Robot-assisted laparoscopic cystectomy may lead to less blood loss, faster recovery, and fewer complications than open cystectomy. It is possible, however, that there may be an increased risk of recurrence or progression from bladder cancer

Where is the study run from?

University of Gothenburg/Sahlgrenska University Hospital (Sweden)

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

September 2019 to September 2028

Who is funding the study?
The study is funded by the Agreement concerning research and education of doctors in Sweden

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019-00717 / 844-18

Study information

Scientific Title
Robotic-Assisted radical Cystectomy vErsus open Radical cystectomy: a randomised non-inferiority trial comparing 3-year recurrence-free survival in patients undergoing cystectomy for urothelial carcinoma of the bladder

Acronym
RACER

Study objectives
Robot assisted laparoscopic cystectomy is non-inferior to open cystectomy with regards to 3-year progression-free survival

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/01/2019, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala, Sweden; +46-10-4750800), ref: 2019-00717 / 844-18

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional file (in Swedish)

Health condition(s) or problem(s) studied
Bladder cancer

Interventions
For both the treatment arms, eligible patients will be offered neo-adjuvant or induction chemotherapy. Randomisation to robot assisted or open surgery will be performed after any preoperative chemotherapy has been finished. Randomisation will be performed through an electronic data capture system, with a computer-generated list. Treatment arms will be stratified by participating centre and muscle-invasive or non-muscle-invasive disease. Both arms will undergo surgery with an identical enhanced recovery protocol.

Participating subjects will receive either robot assisted laparoscopic cystectomy (experimental arm) or open cystectomy (control arm). The urinary deviation can be performed either entirely intra-corporeally or through a small incision extra-corporeally. The type of deviation is at the discretion of the surgeon and patient. All surgeons participating in the study is mandated to have performed at least 10 cystectomies of the relevant type (open or robotic) in the preceding year.

Follow-up will be performed with CT thorax and abdomen, which will be assessed by RECIST criteria, according to the Swedish National Guidelines for urothelial cancer. This follow-up scheme is dependent on the final pathology report, and may be subject to change according to updates in the National Guidelines.

Intervention Type
Other

Primary outcome measure
Progression-free survival at three years following cystectomy

Secondary outcome measures
Surgical outcomes:
1. Rate of complications
2. Blood loss
3. Rate of transfusion
4. Time of stay
Long-term outcomes:
5. Rate of unplanned readmission
6. Quality of life measured by questionnaires FACT-G/Bl-Cys and WHODAS2.0 at baseline, and 3, 6 and 12 months and EQ-5D-5L at baseline and weekly for the first 4 postoperative weeks
7. Total health-care related costs following cystectomy, calculated for the direct and indirect costs related to the surgery for the first 6 months

Overall study start date
01/09/2019

Completion date
01/09/2028

Eligibility

Key inclusion criteria
1. Histologically verified urothelial cancer
2. cT1-4a or BCG-unresponsive CIS
3. N0-1, or N2-3 if response on pre-operative chemotherapy to N0-1
4. Able to sign informed consent

Participant type(s)
All

Age group
Adult

Sex
Both

Target number of participants
488

Key exclusion criteria
1. Distant metastasis (M1)
2. Unfit for either type of procedure
3. Extant ileo- or colostomy
4. Duplicated ureters

Date of first enrolment
04/11/2019

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Sweden

Study participating centre
University of Gothenburg/Sahlgrenska University Hospital
Department of Urology
Bruna Stråket 11B
Gothenburg
Sweden
413 45

Study participating centre
University of Lund/Skåne University Hospital
Department of Urology
Jan Waldenströms Gata 5
Malmö
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Sponsor information

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Sahlgrenska University Hospital

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Sponsor type
University/education

Website
https://www.sahlgrenska.se/en/

ROR
https://ror.org/04vgqjj36

Funder(s)

Funder type
Government

Funder Name
The study is funded by the Agreement concerning research and education of doctors in Sweden.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/06/2029

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as ethical approval does not allow it.

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		10/10/2019	04/11/2019	No	Yes