

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

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<b>Registration date</b> 04/11/2019	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/12/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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?

Dr Henrik Kjölhede

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

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

### **Study type(s)**

Treatment

### **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(s)**

Progression-free survival at three years following cystectomy

### **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

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

**Organisation**  
Sahlgrenska University Hospital

**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

**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?
<a href="#">Participant information sheet</a>		10/10/2019	04/11/2019	No	Yes