

# Standard open radical cystectomy (ORC) versus robotically assisted radical cystectomy (RARC)

<b>Submission date</b> 19/04/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/08/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-of-robotic-assisted-keyhole-surgery-for-bladder-cancer-iroc>

## Contact information

### Type(s)

Public

### Contact name

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

NCT03049410

**Protocol serial number**

33071

## Study information

**Scientific Title**

A phase III multicentre randomised controlled trial to compare the efficacy of Robotically Assisted Radical Cystectomy (RARC) and intracorporeal urinary diversion with Open Radical Cystectomy (ORC) in patients with bladder cancer

**Acronym**

iROC

**Study objectives**

The aim of this study is to compare robotic assisted radical cystectomy versus standard open radical cystectomy to see if one gives better recovery times and less complications than the other.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee North East – Newcastle & North Tyneside 1, 18/01/2017, ref: 16/NE/0418

**Study design**

Randomised; Interventional; Design type: Treatment, Surgery

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Bladder cancer

**Interventions**

Participants are randomised in a 1:1 ratio to one of two groups.

Arm A: Participants undergo a robotically assisted radical cystectomy (RARC).

Arm B: Participants undergo an open radical cystectomy (ORC).

Patients in both groups will be followed up at 5 weeks, 12 weeks, 24 weeks and 1 year post surgery.

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

Number of days alive and out of hospital within 90 days from surgery is assessed by reviewing patient's medical notes and conducting follow-up visits at 5 weeks and 12 weeks after surgery.

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

1. Self-administered WHODAS-2 (12 point) questionnaire at baseline (pre-operative), 5 weeks, 12 weeks, 24 weeks and 1 year after surgery
2. Self-administered EORTC QLQ-BLM30 questionnaire at baseline (pre-operative), 5 weeks, 12 weeks, 24 weeks and 1 year after surgery
3. Self-administered EQ-5D-5L questionnaire at baseline, 5 weeks, 12 weeks, 24 weeks and 1 year after surgery
4. Quantified activity levels: Total steps taken over 7 consecutive days (measured using a wearable tracking device e.g. Fitbit) at baseline (pre-operative), 5 days post-op, 5 weeks, 12 weeks, 24 weeks and 1 year after surgery
5. 30 Second Chair to Stand test: Number of times the patient can stand from sitting in a 30 second interval. This will be conducted in clinic at baseline (pre-operative), 5 weeks, 12 weeks, 24 weeks and 1 year after surgery

The following tools will be used to measure complications:  
Adverse events recorded using the Clavien-Dindo classification.

### **Completion date**

30/09/2021

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 04/07/2017:

1. Participants must be over 18 years of age
2. Male or female
3. Histopathological confirmation of bladder cancer (UCC, SCC, adenocarcinoma or rare variant)
4. CIS or stage pTa or pT1 or  $\geq$ pT2 or mobile bladder mass on bimanual examination under anaesthesia
5. Node status  $\leq$  N1 on imaging criteria or PET -ve outside pelvis
6. ECOG grade 0, 1, 2 or 3
7. Able to give informed written consent to participate

Previous inclusion criteria:

1. Participants must be over 18 years of age
2. Male or female
3. Histopathological confirmation of bladder cancer (UCC, SCC, adenocarcinoma or rare variant)
4. CIS or stage pTa or pT1 or  $\geq$ pT2 or mobile bladder mass on bimanual examination under anaesthesia
5. Node status  $\leq$  N1 on imaging criteria or PET -ve outside pelvis
6. ASA grade 1,2,3 or 4
7. Able to give informed written consent to participate

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

338

**Key exclusion criteria**

Current exclusion criteria as of 04/07/2017:

1. Unwilling to undergo cystectomy
2. Previous abdominal surgery rendering them unsuitable for either iRARC or ORC
3. Patients with upper urinary tract disease
4. Concomitant disease that would render the patient unsuitable for the trial
5. Pregnant or lactating females
6. Previous radiotherapy for bladder cancer

Previous exclusion criteria:

1. Unwilling to undergo cystectomy
2. Previous abdominal surgery other than hernia repair or cholecystectomy
3. Patients with upper urinary tract disease
4. Concomitant disease that would render the patient unsuitable for the trial
5. Pregnant or lactating females

**Date of first enrolment**

01/03/2017

**Date of final enrolment**

31/03/2020

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**University College Hospital**

235 Euston Road

London

United Kingdom

NW1 2BU

**Study participating centre**  
**Royal Hallamshire Hospital**  
Glossop Road  
Sheffield  
United Kingdom  
S10 2JF

## Sponsor information

**Organisation**  
University College London

**ROR**  
<https://ror.org/02jx3x895>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
The Urology Foundation

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from [situ.iroc@ucl.ac.uk](mailto:situ.iroc@ucl.ac.uk)

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		15/05/2022	16/05/2022	Yes	No
<a href="#">Protocol article</a>	protocol	08/08/2018	23/10/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Plain English results</a>			02/08/2024	No	Yes

[Study website](#)

Study website

11/11/2025

11/11/2025

No

Yes