ISRCTN13680280 https://doi.org/10.1186/ISRCTN13680280

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

Submission date	Recruitment status	[_] Prospectively registered
19/04/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/04/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/08/2024	Cancer	

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

Study website
https://www.ucl.ac.uk/surgery/research/situ-trials/iroc/iroc-trial-information

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT03049410

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 a 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 measure
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.

Secondary outcome measures
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.

Overall study start date
18/10/2016

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 ≥pT2 or mobile bladder mass on bimanual examination under anaesthesia

5. Node status ≤ 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 ≥pT2 or mobile bladder mass on bimanual examination under anaesthesia
5. Node status ≤ 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 320; UK Sample Size: 320

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
England

United Kingdom

Study participating centre
University College Hospital
235 Euston Road
London
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NW1 2BU

Study participating centre
Royal Hallamshire Hospital
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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
The Urology Foundation

Results and Publications

Publication and dissemination plan
Planned publication in peer reviewed scientific journals and dissemination of the results at conference presentations and appropriate websites.

Intention to publish date
30/09/2022

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

IPD sharing plan summary
Available on request

Study outputs

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