Study of tumour focused radiotherapy for bladder cancer

Submission date	Recruitment status No longer recruiting	Prospectively registered			
14/10/2015		☐ Protocol			
Registration date	Overall study status Ongoing	Statistical analysis plan			
14/10/2015		[X] Results			
Last Edited	Condition category	[] Individual participant data			
27/11/2025	Cancer				

Plain English summary of protocol

http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-different-ways-of-giving-radiotherapy-for-bladder-cancer-raider

Contact information

Type(s)

Public

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT02447549

Protocol serial number

18868

Study information

Scientific Title

A Randomised phase II trial of Adaptive Image guided standard or Dose Escalated tumour boost Radiotherapy in the treatment of transitional cell carcinoma of the bladder (RAIDER)

Acronym

RAIDER

Study objectives

- 1. Stage I of the study aims to establish the feasibility of Dose escalated Adaptive tumour boost RT in a multi-centre setting
- 2. Stage II of the study aims to establish the toxicity of Dose escalated Adaptive tumour boost RT

Ethics approval required

Old ethics approval format

Ethics approval(s)

London - Surrey Borders Research Ethics Committee, 22/05/2015, ref: 15/LO/0539

Study design

Randomized; Interventional; Design type: Treatment

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bladder cancer

Interventions

Participants are randomly allocated to one of three three groups for a course of radiotherapy:

Group 1: Participants receive standard whole bladder radiotherapy (WBRT)

Group 2: Participants receive standard dose adaptive tumour focused radiotherapy (SART). Three plans (small, medium & large) generated with the standard dose of RT focused on the tumour, sparing the normal bladder from full dose radiation. Pretreatment cone beam CTs will be used to select the best fitting of the three plans prior to treatment.

Group 3: Participants receive dose escalated adaptive tumour boost radiotherapy (DART). Three plans (small, medium & large) generated with a higher dose than standard focused on the tumour and the remainder of the bladder treated to the same dose as in the SART group. Pretreatment cone beam CTs will be used to select the best fitting of the three plans prior to treatment.

Added 27/11/2025:

Additional Data Linkage Information:

Participants from this trial will also be included in the INTERACT project which will link to their data held by NHS England. For more information, please see the INTERACT website: https://www.icr.ac.uk/interact.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Feasibility and safety of the treatment is determined at the end of the treatment period

Key secondary outcome(s))

Ability to deliver SART and DART is determined at the end of the treatment period

Completion date

31/03/2029

Eligibility

Key inclusion criteria

- 1. Written informed consent
- 2. Aged 16 years or over
- 3. Histologically or cytologically confirmed transitional cell carcinoma (TCC) of the bladder
- 4. Unifocal bladder TCC staged T2-T4a N0 M0
- 5. Fit to receive a radical course of radiotherapy
- 6. WHO performance status 0-2
- 7. Willing and able to comply with study procedures and follow up schedule

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

16 years

Upper age limit

100 years

Sex

All

Total final enrolment

345

Key exclusion criteria

Current exclusion criteria as of 09/10/2018:

- 1. Nodal or metastatic disease
- 2. Multifocal invasive disease
- 3. Simultaneous TCC in upper tract or urethra
- 4. Pregnancy
- 5. Active malignancy within 2 years of randomisation (not including non melanomatous skin

carcinoma, previous non-muscle invasive bladder tumours, NCCN low risk prostate cancer (T1 /T2a, Gleason 6 PSA <10), in situ carcinoma of any site)

6. Bilateral Hip replacements

7. Any other conditions that in the Principal Investigator's opinion would be a contra-indication to radiotherapy (e.g. previous pelvic radiotherapy/inflammatory bowel disease)

Previous exclusion criteria:

- 1. Nodal or metastatic disease
- 2. Widespread carcinoma in situ (CIS) or CIS remote from muscle invasive tumour or multifocal invasive disease
- 3. Simultaneous TCC in upper tract or urethra
- 4. Pregnancy
- 5. Active malignancy within 2 years of randomisation (not including non melanomatous skin carcinoma, previous non-muscle invasive bladder tumours, NCCN low risk prostate cancer (T1 /T2a, Gleason 6 PSA <10), in situ carcinoma of any site)
- 6. Any other conditions that in the Principal Investigator's opinion would be a contra-indication to radiotherapy (e.g. previous pelvic radiotherapy/inflammatory bowel disease)

Date of first enrolment

23/09/2015

Date of final enrolment 31/03/2020

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
The Institute of Cancer Research
15 Cotswold Road
Sutton
England
SM2 5NG

Sponsor information

Organisation

The Institute of Cancer Research

ROR

https://ror.org/043jzw605

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/09/2024	11/10/2024	Yes	No
HRA research summary			28/06/2023		No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			13/12/2024	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes