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Study of tumour focused radiotherapy for bladder cancer

Submission date	Recruitment status	[_] Prospectively registered
14/10/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/10/2015	Ongoing	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/12/2024	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

Study website
http://www.icr.ac.uk/our-research/our-research-centres/clinical-trials-and-statistics-unit/clinical-trials/raider

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT02447549

Secondary identifying numbers
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

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 to request a patient information sheet

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.

Intervention Type
Procedure/Surgery

Primary outcome measure
Feasibility and safety of the treatment is determined at the end of the treatment period

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

Overall study start date
23/09/2015

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

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants

Planned Sample Size: 240; UK Sample Size: 180

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
England

United Kingdom

Study participating centre
The Institute of Cancer Research
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Sponsor information

Organisation
The Institute of Cancer Research

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Clinical Magnetic Resonance
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Sponsor type
Research organisation

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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