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A multicentre randomised phase II study of hypofractionated bladder radiotherapy with or without image guided adaptive planning

Submission date 11/09/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/09/2013	**Overall study status** Completed	
Last Edited 05/07/2023	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-trial-to-learn-more-about-weekly-radiotherapy-for-invasive-bladder-cancer-and-to-look-differnt-way-planning-treatment-hybrid

Contact information

Type(s)
Scientific

Contact name
Dr HYBRID Trial

Contact details
Section of Clinical Trials
15 Cotswold Road
Sutton
United Kingdom
SM2 5NG
+44 20 7352 8133
HYBRID-icrctsu@icr.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01810757

Secondary identifying numbers
15216

Study information

Scientific Title
A multicentre randomised phase II study of HYpofractionated Bladder Radiotherapy with or without Image guided aDaptive planning

Acronym
HYBRID

Study objectives
HYBRID aims to collect robust information about the side effects of weekly bladder radiotherapy, and is also investigating whether side effects can be reduced by using scans taken before each weekly treatment to tailor radiotherapy delivery (adaptive radiotherapy).

Ethics approval required
Old ethics approval format

Ethics approval(s)
11/09/2013, ref: 13/LO/1350

Study design
Randomised; 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

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Bladder Cancer; Disease: Bladder (superficial)

Interventions
Participants will be randomly allocated between weekly radiotherapy and weekly adaptive radiotherapy. Both groups will receive the same radiotherapy dose.

1. Adaptive planning, 36 Gray of hypofractionated radiotherapy will be delivered in 6 fractions using the best fitting of 3 plans at each treatment. Plans will be selected and verified by

accredited staff.
2. Standard planning (control), 36 Gray of hypofractionated radiotherapy will be delivered in 6 fractions using standard planning and delivery techniques.

Participants will visit the hospital 4 weeks, 3, 6, 12 and 24 months after radiotherapy to receive treatment for any symptoms and to check whether the cancer has returned. The main aim of HYBRID is to establish whether use of adaptive radiotherapy can reduce nonbladder side effects by reducing the amount of nonbladder tissue exposed to high doses of radiotherapy. HYBRID will also combine the results of both treatment groups to investigate how well weekly radiotherapy controls bladder cancer.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Proportion of patients experiencing severe acute non-genitourinary side effects after radiotherapy; Timepoint(s): Up to 3 months

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2013

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Written informed consent
2. Age =18 years
3. Histologically confirmed invasive bladder carcinoma (T2T4a N0 M0; any histological subtype)
4. Unsuitable for radical cystectomy or daily fractionated radiotherapy for any reason (including performance status, comorbidity, patient refusal)
5. Expected survival more than 6 months
6. WHO performance status 03
7. Willing to undergo post treatment cystoscopy
8. Able to attend post treatment follow up

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
Planned Sample Size: 62; UK Sample Size: 62; Final enrolment: 65

Total final enrolment
65

Key exclusion criteria
1. Nodal or metastatic disease
2. Concurrent 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)
3. Previous pelvic radiotherapy
4. Urinary catheter in situ
5. Any other contraindication to radiotherapy (e.g. inflammatory bowel disease)

Date of first enrolment
15/04/2015

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Section of Clinical Trials, 15 Cotswold Road
Sutton
United Kingdom
SM2 5NG

Sponsor information

Organisation
Institute of Cancer Research (UK)

Sponsor details

Experimental Cancer Medicine Centre Network
Cancer Research
123 Old Brompton Road
London
United Kingdom
SW7 3RP

Sponsor type
Research organisation

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (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
31/12/2019

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results			12/02/2021	No	Yes
Protocol article		26/05/2020	20/06/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article	results	11/12/2020	05/07/2023	Yes	No