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Adaptive Predictive Planning for hypofractioned bLadder radiotherapY

Submission date 27/01/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/02/2009	**Overall study status** Completed	
Last Edited 27/06/2019	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-study-radiotherapy-bladder-cancer-APPLY

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01000129

Secondary identifying numbers
CCR 3122

Study information

Scientific Title
Adaptive predictive planning for hypofractioned bladder radiotherapy: a prospective phase II study

Acronym
APPLY

Study objectives
There is a continued need for adaptive planning in patients receiving radiotherapy for bladder cancer which can be incorporated into the treatment pathway using an adaptive-predictive organ localisation (A-POLO) methodology.

On 01/03/2011 the overall trial end date was changed from 27/01/2011 to 31/12/2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Royal Marsden Research Ethics Committee, 18/12/2008, ref: 08/H0801/137

Study design
Prospective non-blinded non-randomised phase II study

Primary study design
Interventional

Secondary study design
Non randomised study

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
Muscle invasive bladder cancer

Interventions
A prospective phase II study clinically implementing adaptive planning in radiotherapy for bladder cancer. All eligible patients will be treated with new clinical protocol.

All patients will undergo computed tomography (CT) planning scans at 0, 30 minutes post-void (CT1, CT2). The clinical target volume (CTV) will be contoured on each scan, defined as the whole

bladder plus any area of extravesical spread (CTV1, CTV2). A series of three 3-dimensional conformal plans will be generated for each patient according to the following CTV expansion margins:
Plan 1 (standard): planning target volume 2 (PTV2) = CTV1 + 0.5 cm laterally and inferiorly + 1 cm posteriorly + 1.5 cm superiorly and anteriorly
Plan 2 (small): PTV1 = CTV1 + 0.5 cm isotropically
Plan 3 (large): PTV3 = CTV2 + 0.5 cm laterally and inferiorly + 1 cm posteriorly + 1.5 cm superiorly and anteriorly

If the difference in volume between CTV1 and CTV2 is less than 50 cc, PTV3 = CTV1 + 0.75 cm laterally and inferiorly + 1.2 cm posteriorly + 2.5 cm superiorly and inferiorly.

Patients will receive up to six fractions of radiotherapy delivered weekly. Prior to each fraction a cone beam CT scan will be performed followed by online set-up correction. Each PTV contour will be assessed to determine the PTV providing the best fit. The most appropriate contour is that which encompasses the bladder as seen on CBCT + 2 - 3 mm superiorly. The plan selected will be confirmed by a second observer. Treatment is then delivered using the corresponding plan. A post-treatment cone beam image will be taken to ensure that intrafraction motion is accounted for.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Appropriate identification and correction of fractions requiring adaptive planning, assessed at the end of treatment.

Secondary outcome measures
1. Proportion of fractions requiring adaptive planning, assessed at end of treatment
2. Dose-volume histogram (DVH) analysis of CTV coverage using anisotropic margins, assessed at end of treatment
3. Time to local disease progression, measured at 2 years
4. Overall survival, measured at 2 years

Overall study start date
27/01/2009

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Aged greater than 18 years, either sex
2. Histologically confirmed invasive carcinoma of the bladder
3. Patient planned to receive hypofractionated radiotherapy to the bladder
4. No previous pelvic radiotherapy
5. Written informed consent given according to International Conference on Harmonisation of

Technical Requirements for Registration of Pharmaceuticals for Human Use/Good Clinical Practice (ICH/GCP) and national/local regulations

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
32

Key exclusion criteria
Urinary catheter in-situ

Date of first enrolment
27/01/2009

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Cancer Research
Belmont
United Kingdom
SM2 5PT

Sponsor information

Organisation
Institute of Cancer Research (UK)

Sponsor details
123 Old Brompton Road
London
United Kingdom
SW7 3RP

Sponsor type
Research organisation

Website
http://www.icr.ac.uk

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref: C46/A3970)

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

Funder Name
Francis Wain Jewellers Ltd (UK) - charitable donation

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?
Plain English results				No	Yes
Results article	results	01/03/2011		Yes	No