

# Adaptive Predictive Planning for hypofractionated bLadder radiotherapy

<b>Submission date</b> 27/01/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/02/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/06/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-study-radiotherapy-bladder-cancer-APPLY>

## Contact information

### Type(s)

Scientific

### Contact name

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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 hypofractionated 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?
<a href="#">Plain English results</a>				No	Yes
<a href="#">Results article</a>	results	01/03/2011		Yes	No