

A randomised phase II trial of Prostate and pelvis Versus prOsTate Alone treatment for Locally advanced prostate cancer

Submission date 11/02/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/02/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/01/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-2-different-ways-giving-radiotherapy-prostate-cancer>

Study website

<https://www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/clinical-trials/pivotal>

Contact information

Type(s)

Scientific

Contact name

Ms Rebecca Lewis

Contact details

Clinical Trials & Statistics Unit (ICR-CTSU)
Section of Clinical Trials
Brookes Lawley Building
15 Cotswold Road
Sutton
United Kingdom
SM2 5NG

-

PIVOTAL-icrctsu@icr.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT01685190

Secondary identifying numbers

9468

Study information

Scientific Title

A randomised phase II trial of Prostate and pelvis Versus prOsTate Alone treatment for Locally advanced prostate cancer

Acronym

PIVOTAL

Study objectives

PIVOTAL is a non-comparative randomised study which aims to determine the feasibility and toxicity of treating locally advanced prostate cancer with escalated doses of radiotherapy to the prostate and pelvic nodes using intensity modulated radiotherapy (IMRT).

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC, 25/08/2010, ref: 10/H1208/54

Study design

Multicentre randomised interventional non-comparative treatment trial

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: Prostate Cancer; Disease: Prostate

Interventions

1. Pelvis and prostate IMRT: 74 Gray to prostate and 60 Gray to pelvis in 37 fractions over 7.5 weeks
2. Prostate alone IMRT: 74 Gray in 37 fractions over 7.5 weeks

Follow-up length: 24 months

Study entry: single randomisation only

Intervention Type

Other

Phase

Phase II

Primary outcome measure

Acute gastrointestinal (GI) Radiation Therapy Oncology Group (RTOG) grade greater than or equal to 2 toxicity, measured 18 weeks from start of radiotherapy

Secondary outcome measures

1. Biochemical progression, measured throughout follow up
2. Compliance with dose volume constraints, measured throughout follow up
3. Disease-specific survival, measured throughout follow up
4. Local progression, measured throughout follow up
5. Lymph node (regional) progression, measured throughout follow up
6. Overall survival, measured throughout follow up
7. Patient reported outcomes, measured at baseline (pre-randomisation and pre-radiotherapy treatment), week 10, week 18 and at 6, 12, 18 and 2 years
8. Patterns of recurrence, measured throughout follow up
9. Time to distant progression, measured throughout follow up

Overall study start date

01/03/2011

Completion date

28/02/2013

Eligibility

Key inclusion criteria

1. Histologically confirmed, non-metastatic adenocarcinoma of the prostate, previously untreated (other than by neoadjuvant hormonal treatment)
2. National Collaborative Cancer Network locally advanced disease (T3b or T4) or estimated risk of pelvic lymph node involvement greater than or equal to 30% and either:
 - 2.1. Gleason 9 or 10, or
 - 2.2. Gleason 8 and one other high risk feature (T3 disease or prostate specific antigen [PSA] greater than 20), or
 - 2.3. Gleason 7 and 2 high risk features (T3 disease and PSA greater than or equal to 30)
3. World Health Organization (WHO) performance status 0 or 1
4. Normal blood count (Hb greater than 11 g/dl, white blood cell count [WBC] greater than 4000 /mm³, platelets greater than 100,00/mm³)
5. Hormonal therapy for 6 - 9 months duration prior to proposed radiotherapy treatment and PSA less than 4 ng/ml prior to randomisation

6. Testosterone level less than 20 ng/dL (0.7 nmol/L)
8. Patients must be prepared to attend follow up. All patients participating in the Patient Reported Outcomes (PRO) Study must have adequate cognitive ability to complete the PRO questionnaires.
9. Written informed consent
10. Male, aged 18 years or older

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

Planned sample size: 110; UK sample size: 110

Key exclusion criteria

1. Prior pelvic radiotherapy
2. Prior major pelvic surgery (e.g. colectomy, colostomy, cystectomy, prostatectomy)
3. Radiologically suspicious (short axis diameter greater than or equal to 1.0 cm unless biopsied and negative) or pathologically confirmed lymph node involvement
4. Life expectancy less than 5 years
5. Castrate resistant prostate cancer (rising PSA after LHRHa and anti-androgen)
6. Previous active malignancy within the last 5 years other than basal cell carcinoma
7. Co-morbid conditions likely to impact on the decision to treat with radiotherapy (e.g. previous inflammatory bowel disease, previous colo-rectal surgery, significant bladder instability or urinary incontinence)
8. Bilateral hip prosthesis or fixation which would interfere with standard radiation beam configuration

Date of first enrolment

03/06/2011

Date of final enrolment

31/12/2012

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre
Clinical Trials & Statistics Unit (ICR-CTSU)
Sutton
United Kingdom
SM2 5NG

Sponsor information

Organisation
Institute of Cancer Research (ICR) (UK)

Sponsor details
Section of Clinical Trials
15 Cotswold Road
Sutton
United Kingdom
SM2 5NG

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)

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**

The datasets generated during and/or analysed during the current study are/will be available upon request. Contact details are the same as in the contact information section. Clinical data are available for sharing subject to completion of a data sharing application form, approval by the trial oversight committees and completion of a data sharing agreement. As part of the review the trialists would consider whether the existing trial consent covers the application, what anonymisation will be required and whether separate ethics approval would be required.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes
Results article	results	15/07/2015		Yes	No
Results article	results	01/03/2019		Yes	No