ISRCTN48709247 https://doi.org/10.1186/ISRCTN48709247

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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/02/2011	**Overall study status** Completed	
Last Edited 27/11/2025	**Condition category** Cancer	

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

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01685190

Protocol serial number
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

Study type(s)
Treatment

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

Added 27/11/2025:
Additional Data Linkage Information:
Participants from this trial will also be included in the INTERACT project which will link to their data held by NHS England. For more information, please see the INTERACT website: https://www.icr.ac.uk/interact.

Intervention Type
Other

Primary outcome(s)

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit

18 years

Upper age limit
100 years

Sex
Male

Total final enrolment
0

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. Comorbid 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
United Kingdom

England

Study participating centre
Clinical Trials & Statistics Unit (ICR-CTSU)
-
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Sponsor information

Organisation
Institute of Cancer Research (ICR) (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, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

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?
Results article	results	15/07/2015		Yes	No
Results article	results	01/03/2019		Yes	No

Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes