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

| Submission date   | Recruitment status   | [X] Prospectively registered |  |  |
|-------------------|----------------------|------------------------------|--|--|
| 11/02/2011        | No longer recruiting | ☐ Protocol                   |  |  |
| Registration date | Overall study status | Statistical analysis plan    |  |  |
| 11/02/2011        | Completed            | [X] Results                  |  |  |
| Last Edited       | Condition category   | Individual participant data  |  |  |
| 03/01/2019        | 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

#### Contact name

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#### Contact details

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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

#### Intervention Type

Other

#### Phase

Phase II

#### 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

Adult

#### Lower age limit

18 years

#### Sex

Male

#### 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

United Kingdom

England

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

Sutton United Kingdom SM2 5NG

## 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             |