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A phase III randomised controlled trial of prostate and pelvis versus prostate alone radiotherapy with or without prostate boost

Submission date 08/01/2018	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 18/01/2018	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 27/11/2025	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-different-ways-of-giving-radiotherapy-for-cancer-of-the-prostate-pivotalboost#undefined

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
219463

ClinicalTrials.gov (NCT)

Nil known

Central Portfolio Management System (CPMS)
CPMS 34511

Study information

Scientific Title
A phase III randomised controlled trial of prostate and pelvis versus prostate alone radiotherapy with or without prostate boost

Acronym
PIVOTALBoost

Study objectives
The primary objective of PIVOTALboost is to assess whether pelvic lymph node radiotherapy with or without dose escalation to the prostate with HDR, HDR incorporating a focal boost or focal boost IMRT when delivered at multiple centres can lead to improved failure free survival with similar levels of bladder (genitourinary) and bowel (gastrointestinal) side effects experienced by patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/05/2017, London-Chelsea Research Ethics Committee (Bristol Centre, Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, United Kingdom; +44 (0)207 1048055; chelsea.rec@hra.nhs.uk), ref: 17/LO/0731

Study design
Randomized; Interventional; Design type: Treatment, Radiotherapy

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
Participants are allocated to one of the following treatment arms:
A: Prostate alone Intensity-modulated radiation therapy (IMRT)
B: Prostate and pelvic IMRT
C: Prostate IMRT and prostate boost
D: Prostate and pelvic IMRT and prostate boost.
Randomisation into arms C and D depend on the boost volume identified by MRI (suitable for focal boost or not), availability of focal HDR or IMRT and patient suitability in case of HDR

Participants are eligible for entry into one of the following randomisation options according to:
1. Boost volume (whether the tumour volume identified on the staging MRI is suitable for focal boost or not),
2. Suitability and availability of HDR (e.g. patient not suitable for HDR brachytherapy or any other clinical reason) and,
3. Type of focal boost (IMRT or HDR brachytherapy).

In centres with no access to HDR or focal IMRT boost, all patients will enter randomisation option 1 (irrespective of having a suitable boost or not).

Randomisation Option 1 (Pelvic node randomisation): No suitable focal boost volume on the staging MRI* and not suitable for HDR brachytherapy.
Randomisation Option 2a (Pelvic node and whole gland boost): No suitable focal boost volume on the staging MRI* and suitable for HDR.
Randomisation Option 2b (Pelvic node and focal boost randomisation): Suitable focal boost volume.

The study doctor explains whether the patient is suitable for brachytherapy to the whole prostate and /or focal boost treatment. It depends on many factors: the patient's fitness, the position of the prostate in the pelvis, previous prostate surgery, the appearance of the cancer and the availability of the treatment techniques at the local cancer centre.

For patients without cancer nodules suitable for focal boost treatment: Patients without a prostate nodule on the MRI scan can be offered brachytherapy (short term internal radiation) to the whole prostate. This procedure is also called high dose rate (HDR) brachytherapy. This treatment delivers a high radiation dose to the prostate. It is combined with external beam radiotherapy to the prostate (15 fractions) or to the prostate and pelvic lymph nodes (20 fractions).

For patients with cancer nodules suitable for focal boost treatment: The radiotherapy dose can be increased to the area in the prostate containing the cancer; the rest of the prostate receives the standard dose. The focal boost treatment can be given either with HDR brachytherapy or external beam radiotherapy.

The post treatment follow up period is 10 years.

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
Procedure/Surgery

Primary outcome(s)
Failure-free survival is measured by the time to first biochemical failure, recommencement of androgen deprivation therapy, local recurrence, lymph node/pelvic recurrence, distant metastases or death due to prostate cancer for up to 10 years.

Key secondary outcome(s))

1. Time to loco-regional recurrence; time to biochemical failure or prostate recurrence; metastatic relapse free survival; overall and prostate cancer specific survival; time to recommencement of androgen deprivation therapy is measured using clinical assessment of disease status up to 10 years
2. Adherence to dose constraints is measured using collection of radiotherapy treatment doses /parameters at treatment
3. Acute bladder and bowel toxicity is measured using RTOG and CTC (v4.0) adverse event reporting at 3 months
4. Late toxicity is measured using RTOG and CTC (v4.0) adverse event reporting up to 10 years
5. Quality of life is measured using ALERT-B (Assessment of Late Effects of RadioTherapy - Bowel) screening tool, Gastrointestinal Symptom Rating Scale (GSRS), IIEF-5 Questionnaire (SHIM), International Prostate Symptom Score (IPSS), and Expanded Prostate Index Composite-26 (EPIC-26) Short Form questionnaire up to 10 years
6. Health economic endpoints are measured using EQ-5D up to 10 years

Completion date
31/12/2029

Eligibility

Key inclusion criteria
1. Histologically confirmed, previously untreated, non-metastatic adenocarcinoma of the prostate using the Gleason scoring or grade group system (histological confirmation can be based on tissue taken at any time, but a re-biopsy should be considered if the biopsy is more than 12 months old).
2. PSA <50 ng/ml prior to starting ADT.
3. NCCN localised high risk or locally advanced disease: T3a, T3b or T4 N0M0 (clinical and/or MRI) and/or Dominant Gleason 4 or 5 (grade group 3, 4, or 5) and/or PSA >20; or
3.1. NCCN intermediate risk disease: T2b-c N0M0, and/or Gleason 3+4 (grade group 2) and /or PSA 10-20 ng/ml
and Adverse feature, for example: Maximum tumour length (MTL) >6 mm and/or 50% biopsy cores positive and / or PI-RADS score 3, 4 or 5, DIL lesion >10mm axial dimension on staging MRI.
4. Age ≥18 years
5. Signed, written informed consent
6. WHO performance status 0-2 (Appendix 1)

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
2232

Key exclusion criteria
1. Prior radiotherapy to the prostate or pelvis
2. Prior radical prostatectomy
3. Prior ADT for > 6 months at consent (as patients will need to commence radiotherapy at months 3-5 (maximum 7) following start of ADT)
4. Adjuvant docetaxel chemotherapy
5. Radiologically suspicious or pathologically confirmed lymph node involvement
6. Evidence of metastatic disease
7. Life expectancy < 5 years
8. Bilateral hip prostheses or any other implants/hardware that would introduce substantial CT artifacts and would make pelvic node planning more difficult
9. For patients having fiducials inserted: Anticoagulation with warfarin/ bleeding tendency making fiducial placement or surgery unsafe in the opinion of the clinician.
10. For patients being considered for randomisation options C2 and D2 only and are undergoing a planning MRI scan: Contraindication to undergo a MRI scan.
11. For undergoing HDR brachytherapy: long-term anticoagulation therapy which cannot be temporarily stopped, prostate surgery (TURP) with a significant tissue cavity, a history of recent deep vein thrombosis or pulmonary embolus, significant cardiovascular comorbidity, unfit for prolonged general anaesthetic.
12. Medical conditions likely to make radiotherapy inadvisable e.g. inflammatory bowel disease, significant urinary symptoms
13. Previous malignancy within the last 2 years (except basal cell carcinoma or squamous cell carcinoma of the skin), or if previous malignancy is expected to significantly compromise 5 year survival
14. Any other contraindication to external beam radiotherapy to the pelvis

Date of first enrolment
02/01/2018

Date of final enrolment
30/08/2024

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
The Clatterbridge Cancer Centre
The Clatterbridge Cancer Centre Nhs Foundation Trust (Lead Site)
Clatterbridge Road
Bebington
Wirral
England
CH63 4JY

Study participating centre
St. James's University Hospital
Leeds Teaching Hospitals NHS Trust
Beckett Street
Leeds
England
LS9 7TF

Study participating centre
The Royal Marsden Hospita
The Royal Marsden Nhs Foundation Trust
Fulham Road
London
England
SW3 6JJ

Study participating centre
Velindre Cancer Centre
Whitchurch Road
Cardiff
Wales
CF14 2TL

Study participating centre
Lincoln County Hospital
United Lincolnshire Hospitals NHS Trust
Greetwell Road
Lincoln
England
LN2 4AX

Study participating centre

Torbay Hospital
Torbay and South Devon NHS Foundation Trust
Hengrave House
Newton Road
Torquay
England
TQ2 7AA

Study participating centre
Queen Elizabeth Medical Centre
University Hospitals Birmingham NHS Foundation Trust
Edgbaston
Birmingham
England
B15 2TH

Study participating centre
Musgrove Park Hospital
Taunton and Somerset NHS Foundation Trust
Taunton
England
TA1 5DA

Study participating centre
Norfolk and Norwich University Hospital
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
England
NR4 7UY

Study participating centre
Southampton General Hospital
University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
England
SO16 6YD

Study participating centre

Freeman Hospital
The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Freeman Road
High Heaton
Newcastle
England
NE7 7DN

Study participating centre
Addenbrookes hospital
Hills Road
Cambridge
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CB2 0QQ

Study participating centre
Royal Free Hospital
Royal Free London NHS Foundation Trust
Pond Street
London
England
NW3 2QG

Study participating centre
Royal Sussex County Hospital
Brighton and Sussex University Hospitals NHS Trust
Eastern Road
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England
BN2 5BE

Study participating centre
Maidstone Hospital
Hermitage Lane
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England
ME16 9QQ

Study participating centre
Royal Surrey County Hospital
Royal Surrey County Hospital Nhs Foundation Trust

Egerton Road
Surrey
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GU2 7XX

Study participating centre
Ipswich Hospital
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IP4 5PD

Study participating centre
University College Hospital
University College London Hospitals NHS Foundation Trust
250 Euston Road
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NW1 2PG

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
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B15 2GW

Study participating centre
Sherwood Forest Hospitals NHS Foundation Trust
Kings Mill Hospital
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NG17 4JL

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
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S5 7AU

Study participating centre
Highland Health Board
NHS Highland, Assynt House, Beechwood Park, Old Perth Road
Inverness
Scotland
IV2 3BW

Study participating centre
NIHR CLAHRC North Thames
Barts Health NHS Trust
The Royal London Hospital
Whitechapel
London
England
E1 1BB

Study participating centre
North Tees and Hartlepool NHS Foundation Trust
University Hospital of Hartlepool
Holdforth Road
Hartlepool
England
TS24 9AH

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road
Middlesbrough
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TS4 3BW

Study participating centre
Cuh at Colchester General Hospital
Colchester General Hospital
Turner Road

Colchester
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CO4 5JL

Sponsor information

Organisation
Institute Of Cancer Research

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes