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# A comparison of pelvic extended nodal irradiation and stereotactic body radiotherapy for patients with recurrent prostate cancer

**Submission date**
11/06/2024

**Recruitment status**
Recruiting

**Registration date**
23/09/2024

**Overall study status**
Ongoing

**Last Edited**
11/02/2026

**Condition category**
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
Prostate cancer can come back after previous treatment with surgery or radiotherapy in glands (known as lymph nodes) in the pelvis, which is what happened to you. When this happens, there are different treatments that could be used for your cancer, but we do not know for certain which treatment is best. The POINTER-PC study is trying to work this out.

Who can participate?
All participants approached about this study have prostate cancer which has come back in lymph glands in their pelvis.

What does the study involve?
Two different types of radiotherapy could be used. The gland(s) could be treated with focused radiotherapy given in a small number of treatments (5 treatments), which is called stereotactic body radiotherapy (SBRT). Or, both the surrounding pelvis as well as the gland(s) known to be cancerous could be treated with radiotherapy. This is known as pelvis radiotherapy.

What are the possible benefits and risks of participating?
This study will compare pelvis radiotherapy with SBRT to see which is better at stopping the cancer from coming back again. Pelvis radiotherapy is usually given in 20 treatments, but it could be shortened to give it in 5 treatments instead. In the study, we will also check if pelvis radiotherapy can be safely given in 5 treatments instead of 20 treatments. Pelvis radiotherapy might be better than SBRT at stopping the cancer coming back again in the pelvis or in another part of the body. SBRT and pelvis radiotherapy in either 5 or 20 treatments can have side effects. Hormone therapies and chemotherapy also carry a risk of side effects.

Where is the study run from?
The Clinical Trials Research Unit at the University of Leeds (UK)

When is the study starting and how long is it expected to run for?
October 2023 to November 2031

Who is funding the study?
Yorkshire Cancer Research (UK)

Who is the main contact?
The POINTER-PC trial team at POINTERPC@leeds.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-radiotherapy-prostate-cancer-come-back-pointer-pc

# Contact information

### Type(s)
Principal investigator

### Contact name
Prof Ann Henry

### Contact details
Department of Clinical Oncology, St James's University, Beckett St
Leeds
United Kingdom
LS9 7TF
-
A.Henry@leeds.ac.uk

### Type(s)
Public, Scientific

### Contact name
Dr Samantha Noutch

### Contact details
Leeds Institute of Clinical Trials Research (LICTR), Level 10, Worsley Building, Clarendon Way, University of Leeds
Leeds
United Kingdom
LS2 9NL
-
pointerpc@leeds.ac.uk

# Additional identifiers

### Integrated Research Application System (IRAS)
327827

### Central Portfolio Management System (CPMS)
62335

### Protocol serial number
CRCPSC-Jul23/100003

# Study information

## Scientific Title
Pelvis Or Involved Node Treatment: Eradicating Recurrence in Prostate Cancer (POINTER-PC)

## Acronym
POINTER-PC

## Study objectives
1. To compare ENI (ENI-5 and ENI-20) with SBRT for the endpoint of metastasis-free survival.
2. To compare ENI-5 with ENI-20 for the endpoint of patient-reported outcome measure (PROM)-assessed late bowel toxicity at 3 years.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 22/05/2024, East of England – Cambridgeshire and Hertfordshire Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 20 7104 8096; cambsandherts.rec@hra.nhs.uk), ref: 24/EE/0099

## Primary study design
Interventional

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

## Study type(s)
Treatment

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

## Interventions
All participants will receive 12 months of hormone therapy, Androgen Deprivation Therapy (ADT), starting either on the first day of radiotherapy or up to one month before radiotherapy starts.

A computer-generated minimisation program that incorporates a random element will be used to ensure the treatment groups are well-balanced for the following factors:
1. Number of pelvic nodal recurrences
2. The type of PET-CT at diagnosis of recurrence
3. Whether the participant is planned for systemic anticancer therapy in addition to ADT (docetaxel/second-generation androgen receptor antagonist or androgen biosynthesis inhibitor) versus none
4. Site (added 27/01/2026)

Randomisation will be performed centrally using the CTRU automated 24-hour randomisation system. Following confirmation of written informed consent and eligibility, participants will be randomised to receive either stereotactic body radiotherapy, pelvis radiotherapy in 5 fractions, or pelvis radiotherapy in 20 fractions on a 2:1:1 basis, respectively.

Prior to treatment:
Participants will be assessed for their toxicity levels before treatment begins. They will also be required to complete two questionnaires to assess their status and quality of life. Samples for translational research purposes, including blood and tissue samples, will be collected at this time. Consent for blood samples is optional and will be confirmed with the CTRU. Blood samples will be taken at three time points: prior to treatment, upon completion of treatment, and 3 months after radiotherapy. Consent for providing tissue blocks is mandatory, and participants must agree to the collection and sending of tissue blocks to external labs to participate in the study. One FFPE original biopsy or prostatectomy specimen tissue block will be collected at baseline.

On treatment:
Depending on randomisation, participants will receive either stereotactic body radiotherapy or pelvis radiotherapy in 5 or 20 fractions.

Stereotactic body radiotherapy: 30-40 Gy in 5 fractions delivered on alternate days over 2 weeks, targeting the involved nodes.
Pelvis radiotherapy in 5 fractions: 25 Gy in 5 fractions plus a simultaneous integrated boost of 30-40 Gy, delivered on alternate days over 2 weeks, targeting the pelvic nodal area.
Pelvis radiotherapy in 20 fractions: 44 Gy in 20 fractions plus a simultaneous integrated boost of 54 Gy to macroscopically involved node(s), delivered daily over 4 weeks, targeting the pelvic nodal area.
Treatments will be delivered using intensity-modulated RT (IMRT) with daily online image guidance. Additional systemic anticancer therapies (docetaxel/second-generation androgen receptor antagonist or androgen biosynthesis inhibitor) will be allowed post-radiotherapy. The radiotherapy will be delivered Monday to Friday for either 2 or 4 weeks, depending on the treatment.

End of treatment:
Participants will be assessed for toxicity at the end of treatment, and a clinical assessment will be performed. Optional translational blood samples will also be taken at this time.

Follow-up assessments:
Follow-up visits will take place 2 weeks, 6 weeks, 3, 6, 12, 18, 24, 30, and 36 months after the conclusion of radiotherapy. These visits may be conducted in person or over the phone. For phone visits, the participant's GP will need to perform a PSA blood test and, if consented to, collect a blood sample before the appointment. Reminders for completing the quality-of-life questionnaires will be sent 2 weeks and 4 weeks after the initial link is sent, if the questionnaire has not been completed. Data collection will include:
1. A clinical assessment at every follow-up visit
2. Toxicity assessments at 2 weeks, 6 weeks, 3, 6, 12, 18, 24, 30, and 36 months
3. Health-related quality of life questionnaires at 2 weeks, 3, 6, 12, 24, and 36 months (reminders will be sent as needed)
4. Optional translational blood samples at 3 months
5. PSA blood tests at 6 weeks, 3, 6, 12, 18, 24, 30, and 36 months (standard care)

Data analysis:
The statistical analysis will be conducted by CTRU statisticians. A detailed statistical analysis plan will be written before any analysis is undertaken, following CTRU standard operating procedures. The primary endpoint analysis will take place once the final participant reaches their primary endpoint (3 years post-treatment) and once all data have been collected and cleaned.

There will be no formal interim analyses, but an independent data monitoring and ethics committee will review interim safety and accrual data to monitor trial progress. Procedures are in place to detect and address potential "researcher effects" and "researcher bias."

## Intervention Type
Biological/Vaccine

## Phase
Phase III

## Drug/device/biological/vaccine name(s)
Androgen Deprivation Therapy

## Primary outcome(s)
Current primary outcome measure as of 06/11/2024:
1. Metastatic free survival (defined as time from randomisation to progression of the treated node(s), new nodal, bone or visceral metastatic disease, or death due to Prostate Cancer (PCa)) measured using patient records
2. PROM-assessed late bowel toxicity at 3 years, measured using the Expanded Prostate Cancer Index Composite 26-item questionnaire (EPIC-26) bowel function sub-domain.

Previous primary outcome measure:
Metastatic free survival (defined as the time from randomisation to progression of the treated node(s), new nodal, bone or visceral metastatic disease, or death due to Prostate Cancer (PCa)) measured using patient records

## Key secondary outcome(s)
Current secondary outcome measures as of 27/01/2026:
1. Overall survival (defined as the time from randomisation to death from any cause)
2. Biochemical progression-free survival (bPFS, defined as ≥2 ng/ml increase in PSA above the nadir value achieved after completion of RT)
3. Failure-free survival (defined as the time from randomisation to biochemical failure, the commencement of further anticancer therapy for PCa, further nodal, bone or visceral metastases or death from PCa)
4. Patterns of failure: Local, treated-node(s), other regional/ pelvic lymph node(s), para-aortic lymph node(s), other extra-pelvic lymph node(s), bone metastasis, visceral metastasis (liver, lung), other metastasis
5. Urinary and bowel toxicities, measured using the relevant EPIC-26 function and other sub-domains at baseline (pre-randomisation) and 2 weeks, 3 months, 6months, 12 months, 24 months and 36 months post-RT
6. Health-Related Quality of Life (HRQoL), measured using EORTC QLQ-C30 at baseline (pre-randomisation) and 2 weeks, 3 months, 6 months, 12 months, 24 months and 36 months post-RT
7. Clinician-reported toxicity at baseline, end of treatment, 2 weeks, 6 weeks, 3 months, 6

months, 12 months, 18 months, 24 months, 30 months, 36 months post-RT and annually thereafter until 3 years post randomisation of the final participant and maximum acute (≤3 months) and late (>3 months) bowel and urinary toxicity, measured using CTCAE v5.0

Previous secondary outcome measures as of 06/11/2024:
1. Overall survival (defined as the time from randomisation to death from any cause)
2. Biochemical progression-free survival (bPFS, defined as ≥2 ng/ml increase in PSA above the nadir value achieved after completion of RT)
3. Failure-free survival (defined as the time from randomisation to biochemical failure, the commencement of further anticancer therapy for PCa, further nodal, bone or visceral metastases or death from PCa)
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5. Urinary and bowel toxicities, measured using the relevant EPIC-26 function and other sub-domains at baseline and 2 weeks, 3 months, 12 months, 24 months and 36 months post-RT
6. Health-Related Quality of Life (HRQoL), measured using EORTC QLQ-C30 at baseline and 2 weeks, 3 months, 12 months, 24 months and 36 months post-RT
7. Clinician-reported toxicity at baseline, 2 weeks, 6 weeks, 3 months, 6 months, 12 months, 18 months, 24 months, 30 months and 36 months post-RT and maximum acute (≤3 months) and late (>3 months) bowel and urinary toxicity, measured using CTCAE v5.0

Previous secondary outcome measures:
PROM-assessed late bowel toxicity at 3 years, measured using the Expanded Prostate Cancer Index Composite 26-item questionnaire (EPIC-26) bowel function sub-domain.

### Completion date
30/11/2031

## Eligibility

### Key inclusion criteria
Current participant inclusion criteria as of 06/11/2024:
1. Age >=18 years, male
2. Histological diagnosis of prostate adenocarcinoma
3. Previous primary prostate cancer (PCa) treatment (radical prostatectomy [RP], primary/ post-operative radiotherapy [RT] or brachytherapy without previous pelvic nodal RT)
4. Maximum of three PET-CT (PSMA or Choline PET-CT) defined macroscopically-involved pelvic lymph nodes (upper limit of the pelvis is defined as the aortic bifurcation) within 6 months prior to randomisation
5. World Health Organisation (WHO) performance status 0-2
6. Willing to be randomised to stereotactic body radiotherapy (SBRT), ENI-5 or ENI-20
7. Patients must be able to provide study-specific written informed consent
8. Prepared to participate in follow-up by telephone or in-person

Previous participant inclusion criteria:
1. Age >=18 years, male
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7. Patients must be able to provide study-specific written informed consent
8. Prepared to participate in follow-up by telephone or in-person

### 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. Previous pelvic nodal radiotherapy
2. Contraindications to SBRT or ENI (e.g. inflammatory bowel disease)
3. Contraindications to ADT
4. Local recurrence in the prostate gland
5. Para-aortic nodal metastases (above the aortic bifurcation)
6. Meso-rectal nodal metastases
7. Bone or visceral metastases
8. Severe late toxicity relating to primary/post-operative RT
9. Other active malignancy (except non-melanoma skin cancer or other malignancy with a documented disease-free survival for a minimum of 3 years before randomisation)
10. Castrate-resistant disease

### Date of first enrolment
01/12/2024

### Date of final enrolment
30/11/2028

## Locations

### Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

**Study participating centre**
**The Christie NHS Foundation Trust**
550 Wilmslow Road
Withington
Manchester
England
M20 4BX

**Study participating centre**
**Cambridge University Hospitals NHS Foundation Trust**
Cambridge Biomedical Campus
Hills Road
Cambridge
England
CB2 0QQ

**Study participating centre**
**Belfast Health and Social Care Trust**
Trust Headquarters
A Floor - Belfast City Hospital
Lisburn Road
Belfast
Northern Ireland
BT9 7AB

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

**Study participating centre**
**University Hospitals Bristol and Weston NHS Foundation Trust**
Trust Headquarters
Marlborough Street
Bristol
England
BS1 3NU

**Study participating centre**
**The Clatterbridge Cancer Centre NHS Foundation Trust**
Clatterbridge Hospital
Clatterbridge Road
Bebington
Wirral
England
CH63 4JY

**Study participating centre**
**NHS Lothian**
Waverley Gate
2-4 Waterloo Place
Edinburgh
Scotland
EH1 3EG

**Study participating centre**
**Guys and St Thomas' NHS Foundation Trust**
249 Westminster Bridge Road
London
England
SE1 7EH

**Study participating centre**
**Hull University Teaching Hospitals NHS Trust**
Hull Royal Infirmary
Anlaby Road
Hull
England
HU3 2JZ

**Study participating centre**

**South Tees Hospitals NHS Foundation Trust**
James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

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

**Study participating centre**
**United Lincolnshire Hospitals NHS Trust**
Lincoln County Hospital
Greetwell Road
Lincoln
England
LN2 5QY

**Study participating centre**
**East and North Hertfordshire NHS Trust**
Lister Hospital
Coreys Mill Lane
Stevenage
England
SG1 4AB

**Study participating centre**
**Somerset NHS Foundation Trust**
Trust Management
Lydeard House
Musgrove Park Hospital
Taunton
England
TA1 5DA

**Study participating centre**

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

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

**Study participating centre**
**North Middlesex University Hospital NHS Trust**
North Middlesex Hospital
Sterling Way
London
England
N18 1QX

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

**Study participating centre**
**The Royal Marsden NHS Foundation Trust**
Fulham Road
London
England
SW3 6JJ

**Study participating centre**

**Royal Surrey County Hospital NHS Foundation Trust**
Egerton Road
Guildford
England
GU2 7XX

**Study participating centre**
**Torbay and South Devon NHS Foundation Trust**
Torbay Hospital
Newton Road
Torquay
England
TQ2 7AA

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

**Study participating centre**
**Sheffield Teaching Hospitals NHS Foundation Trust**
Northern General Hospital
Herries Road
Sheffield
England
S5 7AU

**Study participating centre**
**East Suffolk and North Essex NHS Foundation Trust**
Colchester Dist General Hospital
Turner Road
Colchester
England
CO4 5JL

**Study participating centre**
**Greater Glasgow and Clyde**
Gartnavel Royal Hospital
1055 Great Western Road

Glasgow
Scotland
G12 0XH

**Study participating centre**
**Lancashire Teaching Hospitals NHS Foundation Trust**
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
England
PR2 9HT

**Study participating centre**
**Royal Cornwall Hospitals NHS Trust**
Royal Cornwall Hospital
Treliske
Truro
England
TR1 3LJ

**Study participating centre**
**University Hospitals of Derby and Burton NHS Foundation Trust**
Royal Derby Hospital
Uttoxeter Road
Derby
England
DE22 3NE

**Study participating centre**
**Mid and South Essex NHS Foundation Trust**
Prittlewell Chase
Westcliff-on-sea
England
SS0 0RY

**Study participating centre**
**Barts Health NHS Trust**
The Royal London Hospital
80 Newark Street
London

England
E1 2ES

**Study participating centre**
**York and Scarborough Teaching Hospitals NHS Foundation Trust**
York Hospital
Wigginton Road
York
England
YO31 8HE

**Study participating centre**
**Maidstone and Tunbridge Wells NHS Trust**
The Maidstone Hospital
Hermitage Lane
Maidstone
England
ME16 9QQ

**Study participating centre**
**Imperial College Healthcare NHS Trust**
The Bays
St Marys Hospital
South Wharf Road
London
England
W2 1BL

**Study participating centre**
**Royal Devon University Healthcare NHS Foundation Trust**
Royal Devon University NHS Ft
Barrack Road
Exeter
England
EX2 5DW

**Study participating centre**
**Velindre NHS Trust**
Unit 2
Charnwood Court
Heol Billingsley

Cardiff
Wales
CF15 7QZ

**Study participating centre**
**East Suffolk and North Essex NHS Foundation Trust**
Colchester Dist General Hospital
Turner Road
Colchester
England
CO4 5JL

**Study participating centre**
**University Hospitals of Leicester NHS Trust**
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

**Study participating centre**
**Southend University Hospital**
Prittlewell Chase
Westcliff-on-sea
England
SS0 0RY

**Study participating centre**
**Queen Alexandra Hospital**
Southwick Hill Road
Cosham
Portsmouth
England
PO6 3LY

**Study participating centre**
**Ipswich Hospital**
Heath Road
Ipswich
England
IP4 5PD

**Study participating centre**
**The Royal Marsden Hospital (surrey)**
Downs Road
Sutton
England
SM2 5PT

**Study participating centre**
**Singleton Hospital**
Sketty Lane
Sketty
Swansea
Wales
SA2 8QA

# Sponsor information

**Organisation**
University of Leeds

**ROR**
https://ror.org/024mrxd33

# Funder(s)

**Funder type**
Charity

**Funder Name**
Cancer Research 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

**Funder Name**
Yorkshire Cancer Research

# Results and Publications

### Individual participant data (IPD) sharing plan
After the final trial results publication, researchers may request access to data from the POINTER-PC Trial Management Group and Leeds Cancer Research UK Clinical Trials Unit.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 26/12/2024 | 17/01/2025 | Yes | No |
| Participant information sheet | version 4.0 | 03/07/2025 | 27/01/2026 | No | Yes |
| Protocol file | version 4.0 | 23/07/2025 | 27/01/2026 | No | No |