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Partial prostate Ablation versus Radical Treatment (PART): Comparing partial ablation of the prostate to treatment or removal of the whole prostate in men with localised cancer of one side of the prostate only

Submission date 28/02/2019	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/03/2019	**Overall study status** Ongoing	
Last Edited 29/05/2025	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-partial-ablation-treatment-for-prostate-cancer-part

Background and study aims
The PART study aims to test whether treating only the part of the prostate containing the prostate cancer is as effective in curing prostate cancer as treating the whole prostate gland, and has fewer side effects. Treatment of the whole prostate gland (known as 'radical' treatment) includes surgical removal, radiotherapy, or brachytherapy (known as 'radical' treatments).
Prostate cancer is the most common cancer in men in the UK. Treatment of the whole prostate ('radical' treatment) is normally offered, even if the cancer is only on one side of the prostate gland. New technologies can now treat the part of the prostate affected by the cancer only (known as 'partial ablation', or PA), destroying the cancer but preserving urinary and sexual functions. PA shows promising results in terms of having minimal side effects in men with low-risk prostate cancer, compared to a policy of 'active surveillance' (i.e. no active treatment). We want to test PA in men with intermediate-risk localised prostate cancer, who would usually be advised to have radical treatment.
The two types of PA in this trial will be Irreversible Electroporation (IRE) and High Intensity Focal Ultrasound (HIFU). IRE is an image-guided tissue ablation technology that induces cell death via short, strong pulsed electric fields. Due to its non-thermal nature, IRE preserves vessels, nerves and extracellular matrix, making it an effective treatment modality for prostate cancer. HIFU uses ultrasound energy focused by an acoustic lens to cause tissue damage as a result of thermal coagulative necrosis and acoustic cavitation. HIFU is available in a number of centres in the UK and is approved by the NHS as a treatment for pancreatic and liver cancer.

Who can participate?
We aim to recruit 800 men aged 18 years or older, with clinically significant prostate cancer, from 10+ hospitals in the UK.

What does the study involve?
Participants will be randomly allocated to either radical treatment (choice of surgery or radiotherapy or brachytherapy, as most appropriate) or PA treatment (IRE or HIFU). All patients will be assessed regularly to check if the treatments have worked, using blood tests and (for the PA arm) repeat imaging and prostate biopsies. If there is any sign of the disease returning or worsening, additional treatments will be discussed and offered. We will compare how well the treatments work by measuring the time it takes for additional treatment to be necessary in the radical treatment arm, or to require treatment of the whole prostate gland, or other prostate cancer-specific treatment, in the PA arm. We will also assess quality of life using questionnaires, and costs to the NHS of each treatment

You will have the opportunity to discuss the PART study with a member of the clinical research team and ask any questions you may have. If you agree to join the PART study, you will be asked to sign the PART study consent form. A research nurse will then ask you about your medical history and medications, and collect some information from your medical records about your diagnosis. You will be asked to fill in some questionnaires about your health-related quality of life. These questionnaires should take no longer than 30 minutes to complete. You will then be randomised to receive either Radical Treatment or Partial Ablation. Randomisation means that patients who agree to participate in the study are randomly allocated to one of the treatment groups. It is important that you only agree to take part if you are prepared to accept either Partial Ablation or Radical Treatment. Whether you are allocated to Partial Ablation or Radical Treatment, you will need to discuss with the doctor which specific treatment option to have. Your doctor may recommend a specific option because of clinical factors such as where the tumour is in the prostate. These clinical factors may be discussed with other doctors within the NHS to ensure you receive the best treatment option for you. All participants in PART will receive regular clinical and research follow-up. The amount of time you are in the PART study will depend on when you join the study. The minimum amount of time you will be part of the study is 1 year and the maximum amount of time you could be in the study is 5 years. Any patient requiring follow up after the study period has finished, will continue as appropriate within NHS care pathways.
Clinical follow-up for all participants will include a blood test for PSA at six weeks after treatment. After that, a PSA test will be done every three months for the first year and annually thereafter, as per routine NHS care. The research team will collect information about your cancer check-ups from your medical notes. This will also include information about any side effects that you experience following treatment. You will also be invited to complete questionnaires about your health and quality of life, which should take no longer than 30 minutes to complete. You can receive these questionnaires at a clinic visit, in the post or via email.
Participants in the Partial Ablation group will also receive an MRI scan one week after treatment, and then an MRI scan with prostate biopsies at six months, one year and up to three years after treatment.

What are the possible benefits and risks of participating?
If you take part in the PART study, there is an equal chance that you will be allocated to either the Partial Ablation group or the Radical Treatment group. It is important that you only agree to take part if you are prepared to accept either Partial Ablation or Radical Treatment. There are differences between the treatments in terms of what they involve and the side-effects that may occur. These will be described in the Patient information sheet; you can consider them carefully

and ask as many questions as you wish at your hospital appointments.
There is some additional follow-up for the research, in addition to usual clinical care. You will also be asked to complete study questionnaires asking about topics you may consider sensitive and private, such as sexual, urinary, and bowel functions. The questionnaires will also ask about any health care services and health care resources you may have used.
These are important issues for future patients, and we hope you will answer them, but you do not have to. If you do not want to continue with the study for any reason, you will be able to withdraw at any time, and you will not be asked to give a reason.
If you are in the study cohort that requires Radiotherapy or Brachytherapy these are part of your routine care. For patients having Radiotherapy, fiducial markers (a medical device or small object placed in or on the body to mark an area for radiation treatment or surgery) may be used at some sites. If you take part in this study you will not undergo any additional procedures. These procedures use ionising radiation to form images of your body and/or provide treatment. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. The chances of this happening to you are the same whether you take part in this study or not.

We cannot guarantee that participating in this study will be of direct benefit to you. We do not yet know if Partial Ablation is as effective as radical treatment and causes fewer side-effects, which is why we are conducting this research. However, the information gathered during this study will help improve treatment options for people with intermediate-risk prostate cancer in the future, by providing critical information about the 'trade-off' between cancer control and side-effects following treatment. This will guide decision-making for doctors and patients in future. You will receive the support of the dedicated research nurse team and you will be able to contact us with any concerns.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
February 2019 to March 2029

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Roxanne Williams, part-trial@nds.ox.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
315065

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HTA 17/150/01, IRAS 315065

Study information

Scientific Title
A randomised controlled trial of Partial prostate Ablation versus Radical Treatment (PART) in intermediate risk, unilateral clinically localised prostate cancer

Acronym
PART

Study objectives
Partial ablation (PA) for unilateral intermediate-risk prostate cancer is a safe and effective alternative to radical treatment, with improved quality of life, but without unduly compromising oncological outcomes. More specifically, we hypothesise that:
1. Organ-preserving treatment with PA offers comparable benefit to radical treatment in prostate cancer control
2. The side-effect profile of PA is favourable compared with radical treatment
3. The 'trade-off' between health-related quality of life (HRQoL) and oncological outcomes for men with localised prostate cancer favours partial ablation compared with radical treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design

Multi-centre two-arm parallel design randomized controlled clinical study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Current interventions as of 18/11/2022:

Participants will be randomised 1:1 to receive either Partial Ablation (PA) treatment or Radical Treatment (RT). Randomisation is done using a randomisation programme provided by Oxford Clinical Trials Research Unit (OCTRU), accessed via the trial instance of REDCap.

Partial Ablation (intervention)
Participants randomised to PA will undergo either irreversible electroporation (IRE) or high intensity focused ultrasound (HIFU). PA treatment planning meetings, attended by, as a minimum, a clinician who administers PA and is able to advise on most suitable PA option, along with a uro-radiologist as necessary, will guide recommendations regarding which PA modality, i. e. IRE or HIFU, or in some cases either, may be used on a case-by-case basis, for patients randomised to the PA arm, based on factors such as prostate size and tumour location. HIFU will be performed using either the Focal One® medical device (manufactured by EDAP TMS) or Sonablate® device (manufactured by Sonacare Medical). Both devices are CE marked and will be used in accordance with their indicated use. The device used will be determined by local availability. HIFU treatment will be performed in accordance with the relevant manufacturer's User Manual. Only trained HIFU clinicians will carry out the procedure on PART study participants. IRE will be performed using the NanoKnife® medical device (manufactured by Angiodynamics). NanoKnife® is a CE marked device and will be used in accordance with its indicated use. IRE treatment will be performed in accordance with the manufacturer's User Manual. Only trained IRE clinicians will carry out the procedure on PART study participants.

Radical Treatment (usual care/comparator)
Participants randomised to radical treatment will receive one of the following usual care treatment options which will be carried out as per local hospital policy:
• Radical prostatectomy (RP)
• Radical radiotherapy (RRT)
• Low dose-rate brachytherapy (LDR-B)
Patients randomised to radical treatment will be able to select which treatment (RP or RRT or LDR-B) they receive following full discussion with their local urologist and oncologist, where all treatment options may be applicable (i.e. participant of appropriate fitness/performance status /age), through shared decision-making. Where a particular radical treatment option is preferred or recommended by the treating clinician (e.g. Radiotherapy, based on age or fitness issues, rather than radical surgery), patients may still be recruited to PART, with a recommendation for a particular radical therapy option if randomised to that arm of the study.

The follow-up for all treatment options will be 3 years.

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Previous interventions:

Intervention arm: partial ablation of the prostate.

Comparator arm: one of standard NHS radical treatment options:
1. Radical prostatectomy
2. Radical radiotherapy
3. Low dose-rate brachytherapy

800 patients will be randomised equally between either partial ablation or radical treatment.

The follow-up for all treatment options will be 3 years.

Intervention Type
Mixed

Primary outcome(s)
Current primary outcome measure as of 18/11/2022:

1. Primary treatment failure determined by oncological outcomes assessed by review of medical history at a minimum of 3 years median follow-up post-randomisation, with at least 12 months post-randomisation follow-up of the last recruited participant
2. Side effect profile and patient-reported outcomes profile measured using Health-Related Quality of Life (HRQoL) as measured by the Patient Oriented Prostate Utility Scale (PORPUS-P) at baseline, 6wks post-treatment and 3mths, 6mths, 12mths post-randomisation, thereafter every 12 months until the end of the study

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Previous primary outcome measure:

1. Oncological outcomes assessed by review of medical history at 3 years median follow-up post-randomisation
2. Side effects profile and patient-reported outcomes assessed by review of medical history and questionnaires at 3 years median follow-up post-randomisation

Key secondary outcome(s))
Current secondary outcome measures as of 18/11/2022:

1. HRQoL using standard, validated patient-reported outcome measures (PROMs) questionnaires: IPSS, EQ-5D-5L, EPIC and MAX-PC at baseline, 6wks post-treatment and 3mths, 6mths, 12mths post-randomisation, thereafter every 12 months until the end of the study
2. Health care resource utilisation and cost-effectiveness in terms of cost per quality-adjusted life year (QALY) at baseline, 6wks post-treatment and 3mths, 6mths, 12mths post-randomisation, thereafter every 12 months until the end of the study
3. Short, medium and long-term serious adverse events related to treatments at 31 days and 3 years
4. Proportion of patients needing repeat PA treatment in the PA group measured using documentation of the need for repeat PA treatment in the PA group – at 1 year post-treatment and 3 years post-treatment (for those that reach this time point in the study's lifetime)

5. Accuracy of current mpMRI imaging and biopsy protocols in determining suitability of patients for PA measured by the proportion of prostatectomy patients who develop high-risk disease or bilateral intermediate disease after histopathological evaluation (only in men who have had RP, including salvage RP)
6. Time to disease progression (including local and distal recurrence) at a minimum 12 months post-randomisation follow-up of the last recruited participant, but will be longer for those recruited early in the study
7. Time to disease-specific and overall mortality at a minimum 12 months post-randomisation follow-up of the last recruited participant, but will be longer for those recruited early in the study

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Previous secondary outcome measures:

1. Quality of life assessed using validated questionnaires at 6 weeks, 3 months, 6 months, 12 months, 24 months and 36 months post-treatment
2. Health resource utilisation assessed using validated questionnaires at 6 weeks, 3 months, 6 months, 12 months, 24 months and 36 months post-treatment
3. Short, medium and long-term effects assessed through review of medical history at 30 days (short term) and 3 years (medium term). We will apply for longer-term follow-up at the end of the main stage of the trial.
4. Proportion of patients needing repeat treatment in the partial ablation group, assessed by review of medical history at 1 year and 3 years
5. Accuracy of mpMRI imaging and biopsy protocols in determining suitability of patients for partial ablation, assessed using review of medical history and histopathological data at 6 weeks post-treatment
6. Longer-term disease-specific and overall mortality assessed using long-term follow-up using national registries

Completion date
01/03/2029

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/11/2022:

1. Age ≥18 years with unilateral clinically significant intermediate-risk Gleason Grade Group 2 or 3 (3+4 or 4+3) PCa, or dominant unilateral clinically significant intermediate-risk PCa and contralateral low-risk low-volume Gleason Grade Group 1 (3+3) PCa:
2. PSA ≤ 20 ng/ml within the last 90 days
3. Pre-biopsy mpMRI scan and bilateral biopsies of the prostate (transrectal or transperineal, and targeted biopsy for visible lesions)
4. Clinically ≤T2b disease judged by results of digital rectal examination, imaging by Multi-parametric Magnetic Resonance Imaging (mpMRI) and biopsy (low-risk Gleason Grade Group 1 lesions on the contralateral side are acceptable)
5. Fit, eligible with a standard of care recommendation for any or all of radical prostatectomy, radical radiotherapy or low dose-rate brachytherapy (LDR-B), and suitable for PA using at least

one of irreversible electroporation (IRE) or high intensity focused ultrasound (HIFU)
6. An understanding of the English language sufficient to receive written and verbal information about the study, its consent process and complete study questionnaires

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Previous inclusion criteria:

1. Unilateral clinically significant intermediate-risk prostate cancer, or dominant unilateral clinically significant intermediate-risk prostate cancer and small contralateral low-risk low-volume prostate cancer:
1.1. Grade Group 2 or 3 (Gleason Grade 3+4 or 4+3) disease
1.2. And/or >4 mm cancer core length in any one core irrespective of Grade Group
1.3. PSA ≤20 ng/ml
1.4. Clinically ≤T2b disease judged by results of digital rectal examination and imaging by mpMRI
2. Prostate volume <70 cm3 and ≥25 cm3
3. Fit, eligible with standard of care recommendation for RP, RRT or LDR-B
4. Life expectancy of ≥10 years
5. No concomitant cancer and no previous active treatment for prostate cancer
6. Pre-biopsy mpMRI scan and biopsy (transrectal targeted guided by presence of PIRADS lesions +/- systematic biopsy, or template transperineal mapping biopsy)
7. Understanding of the English language sufficient to receive written and verbal information about the trial, its consent process and complete study questionnaires

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
Current exclusion criteria as of 18/11/2022:

1. Taking part in another therapeutic PCa clinical trial or has been involved in such trials within the previous 4 months (N.B. the TRANSLATE trial is a diagnostic trial and co-enrolment is permitted)
2. PSA > 20 ng/ml within the last 90 days
3. Unfit for radical treatment or general anaesthesia or cannot tolerate transrectal ultrasound
4. In the opinion of the treating physician, has a contraindication to either HIFU or IRE
5. Not suitable for mpMRI or have a single or bilateral hip replacement
6. Has evidence of extraprostatic extension by mpMRI, or clinical or radiological ≥T3 disease
7. Concomitant cancer or previous active treatment for PCa

8. Evidence of metastatic disease
9. Bilateral intermediate risk disease or higher
10. Low-risk (Gleason Grade Group 1) disease only, or high-risk (Grade Group ≥4) PCa only
11. History of acute urinary retention within the last 6 months prior to entry to the study
12. Prostatic calcification and cysts causing ultrasonic shadowing or greater than 1cm (for HIFU)
13. History (within 3 years) of inflammatory bowel disease or any condition that may increase the risk of recto-urethral fistula formation (for HIFU)
14. Has known hypersensitivity to pancuronium bromide, atracurium or cistracurium, or any medical condition such that muscle relaxation cannot be administered as part of a general anaesthetic
15. Has a history of bladder neck contracture
16. Had active treatment for a malignancy within 3 years, including malignant melanoma, except other types of skin cancer
17. Has any active implanted electronic device (e.g., pacemaker)
18. Is unable or unwilling to be catheterised
19. Has had prior or current PCa therapies
20. Has had prior transurethral prostatectomy (TURP), stricture surgery, urethral stent or prostatic implants
21. Has had prior major rectal surgery (except haemorrhoids)
22. Is actively bleeding, is anticoagulated or on blood thinning medications that cannot be stopped for the peri-operative period for a PA procedure, or has a significant bleeding disorder that may affect the peri-operative period as judged by the clinical staff.
23. Unable to give consent to participate in the study as judged by the clinical staff
24. Wishing to maintain future fertility

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Previous exclusion criteria:

1. Unfit for radical treatment or general anaesthesia, or cannot tolerate transrectal ultrasound
2. Bilateral Intermediate risk disease or higher
3. Low-risk disease (Grade Group 1, PSA ≤10 ng/ml, <4 mm total cancer on biopsy) or high-risk disease (Grade Group ≥4, PSA >20 ng/ml, ≥T2c stage)
4. Clinical T3 prostate cancer (i.e. extra-capsular prostate cancer) on digital rectal examination or mpMRI, or evidence of metastatic disease
5. Prostate volume ≥70 cm3 or <25 cm3
6. Previous active therapy for prostate cancer
7. History of sun hypersensitivity or photosensitive dermatitis or latex allergy
8. History of acute urinary retention within 6 months of study entry or who have undergone a Transurethral Resection of the Prostate (TURP) for symptomatic lower urinary tract symptoms, or with metal implants/stents in the urethra, or with a history of a urethral stricture
9. Conditions requiring medication with potential photosensitizing effects (tetracyclines, quinolones, sulphonamides, phenothiazines, sulfonylurea hypoglycaemic agents, thiazide diuretics, griseofulvin, and amiodarone), if these treatments could not be stopped at least 10 days before and for 3 days after the partial ablation procedure or replaced by treatments without photosensitizing properties
10. Anticoagulant drugs (e.g., warfarin) that could not be withdrawn during the 10 days prior to the partial ablation procedure or antiplatelet drugs (e.g. aspirin) that could not be withdrawn during the 10 days prior to the partial ablation procedure and 3 days after the partial ablation procedure

11. Prostatic calcification and cysts that interfere with the effective delivery of partial ablation
12. Renal impairment and/or a Glomerular Filtration Rate (GFR) <35 ml/min
13. Men unable to give consent to participate in the trial as judged by the clinical staff

Date of first enrolment
01/03/2023

Date of final enrolment
01/03/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
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Study participating centre
Churchill Hospital
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University College London Hospital
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Study participating centre

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Study participating centre
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Study participating centre
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 3.0	15/05/2024	22/10/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes