A randomised controlled trial of Partial prostate Ablation versus Radical Treatment in intermediate-risk, unilateral clinically localised prostate cancer

Participant Information Sheet

Version 5.0, 09 Oct 2025

We would like to invite you to take part in a research study called PART. Before you decide whether or not you would like to take part, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information sheet and discuss it with others if you wish. If there is anything that is not clear or if you would like more information, please ask us. You do not have to decide straight away.

Why is the PART study being done?

The PART study compares two approaches to treating intermediate-risk prostate cancer: Partial Ablation and Radical Treatment. Figure 1 provides an overview of these treatments.

Figure 1: Overview of Partial Ablation and Radical Treatment

Partial Ablation Treats the cancer cells in the prostate:		**Radical Treatment** Treats the whole prostate gland:		
HIFU High intensity ultrasound focused on cancer	**IRE** Electrical pulses focused on cancer	**Surgery** Operation to remove prostate	**Radiotherapy** Beams of radiation at the prostate	**Brachytherapy** Radiation seeds placed in prostate

The PART study will investigate how Partial Ablation compares to Radical Treatment in managing intermediate-risk prostate cancer affecting one side of the prostate.

- **Partial Ablation** (also called Focal therapy or PA) aims to destroy (ablate) all the cancer cells in one side of the prostate gland using techniques that are less invasive, such as High Intensity Ultrasound (HIFU) or Irreversible Electroporation (IRE) (also called Nanoknife)..
- **Radical Treatments** are surgery (prostatectomy), radiotherapy, or brachytherapy. They are called 'Radical Treatments' because they aim to remove or destroy all the cancer cells that might be present in the whole prostate gland, so that they cannot grow or spread.

The study aims to compare Partial Ablation with Radical Treatment in relation to:

(a) Preventing cancer growing, coming back, or spreading outside the prostate gland

(b) Assessing damage to nearby nerves and organs that can cause sexual, urinary, or bowel problems after treatment (functional and quality-of-life outcomes).

The PART study aims to recruit 306 patients from hospitals across the UK. The results of the study will provide detailed information to help patients, clinicians and policymakers decide which treatment to have for intermediate-risk prostate cancer in the future.

What is intermediate-risk prostate cancer?

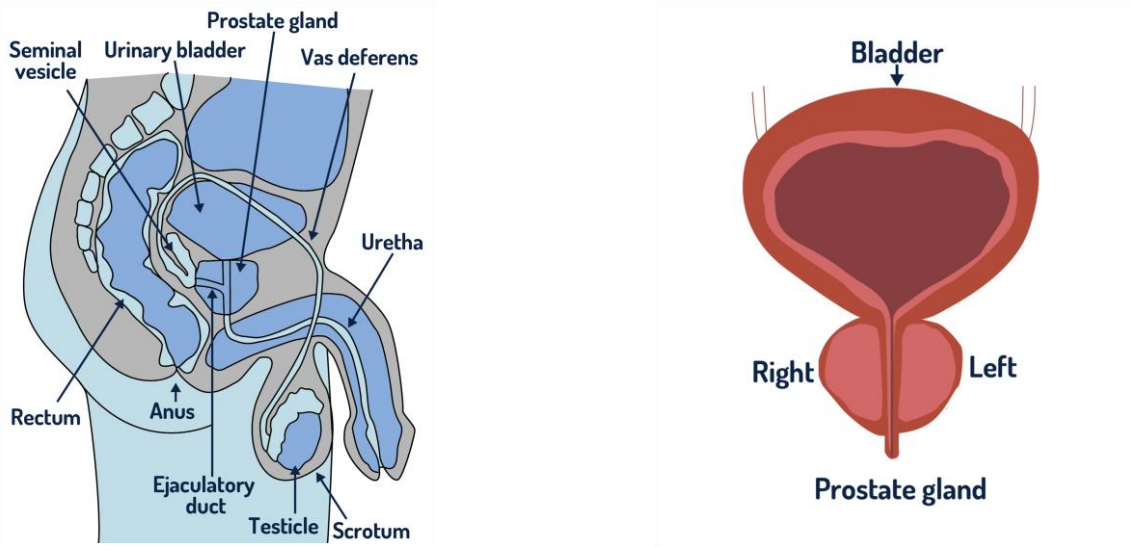
Prostate cancer is the most common cancer in men. Many prostate cancers are confined within the prostate gland ('localised') and grow very slowly. These are labelled 'low-risk' because they are unlikely to grow fast enough, or spread elsewhere, to cause any harm in a man's lifetime. Cancers that are more likely to grow quickly and spread outside the prostate gland are called 'high-risk'. The kind of prostate cancer you have is called 'intermediate-risk', unilateral (it is only on the left or right side of the prostate). Intermediate-risk cancers are in between high- and low-risk – they have some potential to grow and spread but are unlikely to do so for a few years or longer.

You do not need to rush to decide what to do next. You have time to consider your treatment options and whether or not to participate in the PART research study.

What treatment options are available?

Figure 2: A) shows the location of the prostate gland, deep in the pelvis.
B) shows the two halves of the prostate, unilateral cancer is only on one side.

A **B**



The following management options are approved by NICE (UK National Institute of Health and Care Excellence) for intermediate-risk prostate cancer:

Active surveillance

Active surveillance is a potential option for some men with intermediate-risk prostate cancer. With active surveillance, you would have regular Prostate Specific Antigen (PSA) tests, scans and repeat MRI and biopsies to check that the cancer is not growing quickly or spreading. If there is evidence that this is happening, you can then have treatment for the cancer, but otherwise you would remain on active surveillance and have regular tests. If you want to consider active surveillance, please discuss this further with your doctor. You can only participate in the PART study if you and your doctor agree that you should have treatment of the prostate now. If your doctor recommends you have active surveillance, the PART study is not for you.

Radical Treatments

Radical Treatments for intermediate-risk prostate cancer are surgery (prostatectomy), radiotherapy or brachytherapy. They are called 'Radical Treatments' because they aim to remove

or destroy all the cancer cells that might be present in the whole prostate gland, so that they cannot grow or spread. The treatments work in different ways to achieve the same outcome. Surgery removes the whole prostate gland containing the cancer in an operation. Radiotherapy destroys the cancer with radiation targeted at the prostate through x-ray beams. Brachytherapy destroys the cancer with radiation from seeds placed throughout the prostate gland. With all these options, the whole prostate gland is treated.

Radical Treatments have been shown in previous studies (including a UK study called ProtecT) to greatly reduce the risk that cancer will grow or spread outside the prostate gland compared with active monitoring or surveillance. However, it has also been shown that each of the Radical Treatments can damage the nerves and organs close to the prostate gland and cause side-effects. All three Radical Treatments can cause problems with erections and other aspects of your sexual life. Radiotherapy and brachytherapy can cause some bowel and other urinary problems. Surgery can cause urinary leakage (incontinence) in the short- or long-term. After surgery, the removed prostate gland can be examined carefully to find out whether all the cancer has been removed. This is not possible with Radiotherapy or Brachytherapy because the prostate gland remains in place. Each of the Radical Treatments has its own advantages and disadvantages. More details are given later in this information sheet, and you will be able to discuss these details with your doctor.

Partial Ablation

New technologies called 'Partial Ablation' have now been developed to focus treatment only on the side of the prostate containing the cancer cells. Partial Ablation aims to destroy (ablate) all the cancer cells in one side of the prostate gland. The other side of the prostate is left alone. Studies have shown that Partial Ablation can destroy low-risk cancer cells in the prostate. It may also cause less damage to surrounding nerves and organs than Radical Treatments. This may mean that men receiving Partial Ablation could experience fewer sexual, urinary, and bowel problems than those having Radical Treatments.

The Partial Ablation techniques that are being used in the PART study are:

- High Intensity Focused Ultrasound (HIFU). HIFU uses a probe to focus a beam of ultrasound energy to destroy the cancer cells.
- Irreversible Electroporation (IRE). IRE uses probes to deliver high voltage electrical pulses to destroy the cancer cells.

Currently NICE recommends that both HIFU and IRE (Nanoknife) as partial ablation treatments for prostate cancer are safe, and that more evidence is needed to assess their efficacy (https://www.nice.org.uk/guidance/ipg756) (https://www.nice.org.uk/guidance/IPG768). Partial ablation for prostate cancer can be used by clinicians outside of formal trials if they regularly collect data to assess outcomes. The results of the PART study will inform recommendations for widespread use of partial ablation throughout the NHS; currently, it is available at only a few specialist centres.

Why have I been invited?

You have been invited to participate in the PART study because specialists have confirmed that you have intermediate-risk prostate cancer in one side of your prostate gland. These doctors believe that either Partial Ablation or a Radical Treatment may be good treatment options for you. As these treatments have not been directly compared before, doctors are not able to advise you which treatment would be best for you. This is why we are providing you with information so you can consider whether you would like to take part in the PART study.

Do I have to take part?

No. It is completely up to you to decide whether to participate in any aspect of the PART study. If you take part, you can later withdraw without giving a reason. If you do not want to take part or withdraw, this will not affect your clinical care in any way.

What will happen to me if I decide to take part in the PART study?

Below is a full description of what happens if you participate in the PART study (there is also a summary in the Study Flowchart on the next page):

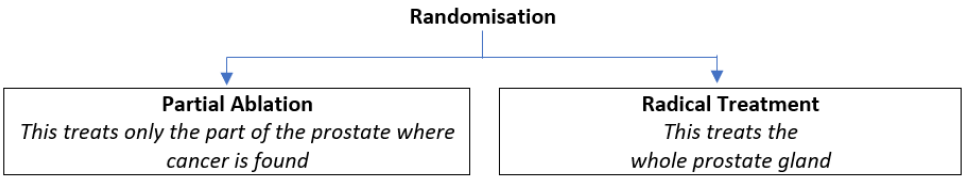
Consent and Baseline measurements

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.

Randomisation

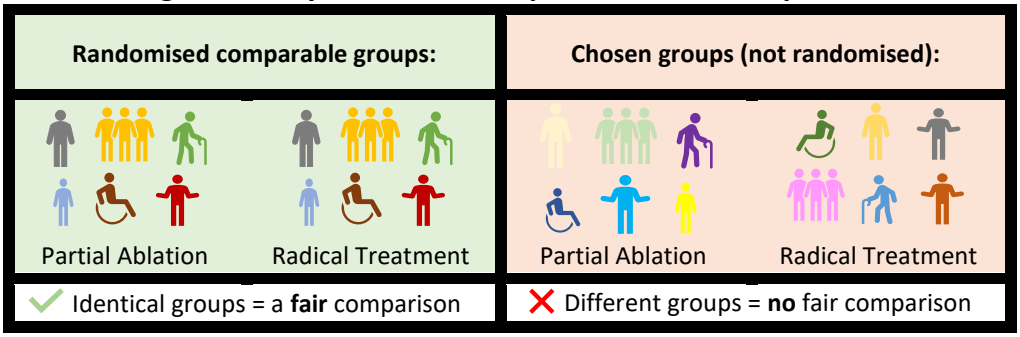
PART is a randomised study. In this type of study, there is a direct comparison between people who have Partial Ablation (by HIFU or IRE) or Radical Treatment (by surgery, radiotherapy or brachytherapy). The only way we can compare these treatments fairly is by dividing participants into two groups that are as similar as possible by a process called randomisation. 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. An outline of randomisation in the PART study is provided in Figure 3 below.

Figure 3: Randomisation in the PART study



Randomisation is the only way to ensure that the groups are as similar as possible to each other and that there are equal numbers in each treatment group. If you or your doctor choose a treatment, the groups would not be the same.

Figure 4: Why randomisation provides a fair comparison



Study Flowchart

Figure 5: Flowchart outlining the PART study.

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. Usually, you will be able to have radical treatment in the hospital where you received your diagnosis. If this is not available, you may need to travel to another hospital, as would be the case in NHS standard of care. Both forms of Partial Ablation may not be available at a hospital nearby, and you may be advised by your doctor to travel to another hospital participating in the PART study to have the partial ablation treatment (HIFU or IRE).

Your doctor will provide you with up-to-date evidence about each option and you will be able to discuss all these issues in detail to decide which treatment option to have.

What does treatment involve?

Table 1 below outlines the key information about the two treatments so that you can see the similarities and differences between them.

Table 1: Similarities and differences between Partial Ablation and Radical Treatments

	Partial Ablation (HIFU or IRE)	Radical Treatment (Surgery, Radiotherapy, or Brachytherapy)
Area treated	The part of the prostate where intermediate-risk cancer is found	The whole prostate gland
Time to treatment	Treatment should start by around six to eight weeks and within 12 months of randomisation.	Treatment should start by around six to eight weeks and within 12 months of randomisation.
Location of treatment	HIFU and IRE are not available in all hospitals. You might need to travel to another hospital to receive treatment	Radical treatments are not available in all hospitals. You might need to travel to another hospital to receive treatment
Anaesthetic	General anaesthetic (to put you to sleep).	**Surgery and Brachytherapy:** General anaesthetic (to put you to sleep). **Radiotherapy:** no anaesthetic
Details of the procedure	**High Intensity Focused Ultrasound (HIFU):** A probe is inserted in the rectum and high-intensity ultrasound is targeted at the areas with cancer. The focused ultrasound heats the tissue and destroys the cancer. **Irreversible Electroporation (IRE):** Probes are inserted through the skin between the back passage and the scrotum into the prostate under ultrasound guidance. Electrical pulses are targeted at the areas with cancer. IRE causes cancer cell death by using electrical current to create tiny holes in the cell membranes.	**Surgery:** The prostate gland with the cancer inside is removed. The operation is usually robot-assisted with keyhole access (small cuts). Sometimes it has to be done with a larger single cut (open access). **Radiotherapy:** Hormone therapy may be given for 3-6 months before radiotherapy, and for up to 3 years afterwards, to shrink the cancer. High-energy x-ray beams are targeted at the prostate to destroy the cancer cells. **Brachytherapy:** Small metal seeds which emit radiation are placed in the prostate gland. The radiation in the seeds destroys the cancer cells.
How long does the treatment take?	**HIFU:** the procedure takes 1-2 hours. **IRE:** the procedure takes 1-1½ hours.	**Surgery:** the operation takes around 3 hours. **Radiotherapy:** Each treatment takes 2-3 minutes in the radiotherapy suite on 5 days per week for 4-8 weeks. **Brachytherapy:** the procedure takes around 2 hours.

Is there an overnight stay in hospital?	Can be done as a day-case, sometimes a one-night stay is required.	**Surgery:** yes, usually 1–2-night stay. **Radiotherapy**: Treatment is given as an outpatient so no overnight stay. **Brachytherapy:** sometimes as a day-case or with one-night stay.
Is a catheter placed to drain urine?	A catheter is placed and remains for at least 48 hours and up to one week before removal.	**Surgery:** A catheter is placed and remains for 1-3 weeks before removal. **Radiotherapy:** no catheter. **Brachytherapy:** A catheter is placed, and usually removed before discharge.
How long does recovery take?	You should be able to return to most usual activities within 2-3 weeks.	**Surgery**: you should allow around 5 weeks for recovery. **Radiotherapy and Brachytherapy:** You should be able to return to most usual activities within 2-3 weeks.

What are the potential side-effects of treatments?

Treatments can cause damage to nerves and organs at the time of the treatment or afterwards – called 'side-effects'. Every patient is at risk of experiencing some side-effects (see Table 2 on the next page) but some might not experience any while others may experience several. There are well-known side-effects that can occur after Radical Treatments, and growing evidence about the side-effects from Partial Ablation. Some side-effects can be managed with medications or other simple strategies at home, although some require treatment in hospital. Side-effects can affect aspects of your daily life. Your clinical team will monitor you after your treatment for any side effects and you will be kept fully informed about management options.

Table 2: Side-effects that may be experienced following treatments

	Partial Ablation ***(HIFU or IRE)***	**Radical Treatment** ***(Surgery, Radiotherapy, or Brachytherapy)***
Side-effects that may be experienced	Side-effects from Partial Ablation treatments have been recorded from centres who already offer this. They may include: **High Intensity Focused Ultrasound (HIFU)** • Risks of having an operation, such as discomfort or pain, bleeding, infection, and effects of anaesthetic. • Some urinary problems, including a risk of urinary leakage in 1 in 100, which in some cases may require surgical treatment. • Some sexual problems (particularly with erections) – although 9 in 10 men who don't need tablets for erections before partial ablation treatment, will keep	Side-effects from Radical Treatments are very well recorded in research studies and include: **Surgery** • Risks of having a major operation, such as pain, bleeding, infection, and effects of anaesthetic. • Urinary problems, including a risk of urinary leakage of 1 in 5, which in some cases may require surgical treatment. • Sexual problems (particularly erectile dysfunction) for up to 9 in 10 immediately, and up to 8 in 10 in the longer term, depending on whether the nerves responsible for erections are preserved. • Loss and ejaculation and Infertility as the prostate and seminal vesicles are removed. **Radiotherapy**

	erections, with 3 in 10 needing tablets to help with erections • 3 in 10 men may lose ejaculation, and most men will notice that the volume of ejaculate is less than before treatment • Fertility can be preserved but if you are keen to have children in the future please discuss this with your doctors **Irreversible Electroporation (IRE)** • Risks of having an operation, such as pain, bleeding, infection, and effects of anaesthetic. • Bruising near where the needles are put into the prostate. • Some urinary problems, including a risk of urinary leakage in 1 in 100 men • Some sexual problems (particularly with erections) – although 9 in 10 men who don't need tablets for erections before partial ablation treatment, will keep erections, with 3 in 10 needing tablets to help with erections • 3 in 10 men may lose ejaculation, and most men will notice that the volume of ejaculate is less than before treatment • Fertility can be preserved but if you are keen to have children in the future please discuss this with your doctors • 12 months after Partial Ablation treatment, repeat MRI imaging will be performed and repeat prostate biopsies will need to be taken. The prostate biopsy technique is likely to be the same as received during diagnosis. Prostate biopsies can have side effects including pain/aching; blood in urine, semen, and faeces; and risk of infection.	• Risks of fatigue from treatments. • Some sexual problems (particularly with erections) for about 9 in 10 if taking hormones, fewer without hormones, with some recovery. Infertility as radiation affects the prostate and seminal vesicles. • Some problems with urinating more often during the day and night initially, usually resolving. • Some bowel problems, such as loose or bloody stools initially, usually resolving. • Some longer-term risks of faecal leakage and development of other cancers. **Brachytherapy** • Risks relating to having an operation (pain, infection, bleeding), including effects of anaesthetic. • Some sexual problems (particularly with erections) for about 4 in 10 men, usually resolving. Infertility as radiation affects the prostate and seminal vesicles. • Some problems with urinating more initially, but resolving. • Some bowel problems, usually resolving. • Some longer-term risks of development of other cancers

What happens if the cancer grows, comes back, or spreads?

There is a risk that the cancer may grow, come back, or spread despite treatment for intermediate-risk prostate cancer. Whichever treatment you have, you will be monitored carefully by the clinical and research teams. After the study has finished, you will continue to be monitored by your clinical care team. If your PSA blood test or other test results suggest that the cancer might have grown or spread, the clinical care team will organise scans, biopsies, or other tests needed to assess things further. You will be fully informed about what is happening and the treatment options available. You should always contact your GP or a member of the study team if you have any concerns at any time.

What treatments could I have if my cancer grows, comes back, or spreads?

If there is evidence from tests that the cancer has grown, come back, or spread, there are clear plans for further treatment. Your doctor will explain the details in your particular situation.

If you received Partial Ablation (HIFU or IRE) initially, the next treatment may include a repeat Partial Ablation if appropriate, or it could be surgery, radiotherapy, hormone therapy, or chemotherapy - depending on test results. Radical prostatectomy after partial ablation or radiotherapy can be more difficult and could have worse cancer outcomes than having radical prostatectomy as a first option.

If you received Radical Treatment by Surgery, Radiotherapy or Brachytherapy, the next treatment might be a different salvage therapy, sometimes using partial ablation, or surgery or radiotherapy or possibly hormone therapy or chemotherapy - depending on test results.

Key issues being investigated in the PART study

There are two key issues being investigated in the PART study: (a) the risks of cancer growing, coming back, or spreading, following Partial Ablation and Radical Treatments, and (b) the side effects caused by these treatments. Previous research has not provided clear evidence about these important issues – this is why we are doing the PART study. It is known from the UK ProtecT study that over a 10-year period for men with low- or intermediate-risk localised prostate cancer, cancer spreads in 2-3 in every 100 men who have Radical Treatment (surgery, brachytherapy, or radiotherapy) and 6 in every 100 men who have active monitoring. The risk of cancer spreading for men who have Partial Ablation is not known. Doctors believe the risk may be at a similar level to Radical Treatment, and that Partial Ablation could have a lesser impact on sexual, urinary and bowel function than Radical Treatments. A precise understanding of how partial ablation compares with radical therapy in these ways, is why the PART study is needed. There are advantages and disadvantages with each of the treatments. These are the issues you need to weigh up when considering whether to take part in the study. All patients will be well cared for and followed up by the medical team whatever you decide to do.

What is the plan for follow up in the PART study?

All patients 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 patients 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 18M, at 24M, then 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. Any research visits will be scheduled to coincide with clinical visits where possible. Some appointments may be done in person, or remotely by telephone.

Patients in the Partial Ablation group will also receive an MRI scan one week after treatment, and then an MRI scan with prostate biopsies at one year and up to three years after treatment. MRI is

safe and non-invasive and does not involve any ionising radiation (x-rays). However, because they use a large magnet to work, MRI scans are not suitable for everybody. Because of this, you will be asked pre-screening safety questions to help determine if you are able to have an MRI. For example, if you suffer from claustrophobia, you would not be scanned. Normally, MRI scanning for research purposes would not be performed without further investigation if you have a heart pacemaker, mechanical heart valve, mechanical implant such as an aneurysm clip, hip replacement, or if you carry other pieces of metal that have accidentally entered your body. As some of the scans can be noisy, your clinical team may give you earplugs, head padding or headphones to make this quieter for you. It is important that these are fitted correctly as they are designed to protect your ears. If you think you might be claustrophobic, please talk to the researcher in advance, or let the person operating the scanner know before you start. In preparation for your scan and for your comfort and safety, your clinical team may ask you to change into pocketless and metal free "pyjama-style" top and trousers, which are available in a range of sizes. You may keep your underwear and socks on, but you will need to remove underwire bras. If you have a suitable non-wired bra you may wear this instead. Do not wear any fabrics that contain metallic threads or are silver impregnated (often marketed as anti-microbial/bacterial or anti-odour). Metal jewellery, including body piercings, must also be removed. While very rare, tattoos can occasionally warm up in the scanner. Please inform the person operating the scanner immediately if you feel any heating. If you have a new tattoo, you should not take part in a scan until 48 hours after receiving the tattoo. Eye shadow and mascara should also be avoided, since some types contain materials that can interact with the magnetic field. If you wish to wear eye makeup to your scan, we can provide makeup removal wipes but you are advised to bring your own makeup to reapply. Lockers are provided to secure your personal belongings and clothing. You will be introduced to the scanner carefully and allowed to leave at any stage. Whilst in the scanner you will have a call button, which you can press if you need to stop the scan or speak with the person operating the scanner.

It is important to note that we do not carry out scans for diagnostic purposes, only for research. Our scans are not routinely looked at by a doctor and are therefore not a substitute for a doctor's appointment. Occasionally, however, a possible abnormality may be detected. In this case, we would have the scan checked by a doctor. If the doctor felt that the abnormality was medically important, you would be contacted directly and further assessment arranged as necessary. You would not be informed unless the doctor considers the finding has clear implications for your current or future health. All information about you is kept strictly confidential.

N.B. In the PART study all MRI scans are looked at by your doctor and research team.

The Information Study

We may also ask if we can audio-record discussions you have with healthcare professionals about the PART study. This is called the 'Information Study' and will help us to understand how information is communicated to patients, and how patients make decisions about whether to take part in research. You will be given a separate information sheet about this. The Information sub-study is optional. You can choose to take part in the main PART study only if you wish. Your appointment can still go ahead if you do not want to be audio-recorded.

You may also be invited to an interview with a researcher to discuss your experiences in more detail. This will only happen if you agree and provide written permission for the interviewer to contact you to arrange an interview at a time and place convenient to you - in person, over the telephone, or online. All parts of the Information Study are optional.

What will happen to me if I decide not to take part in the PART study?

If you decide not to take part in the PART study, you will discuss with your doctor whether to have surgery, external beam radiotherapy, brachytherapy or partial ablation at one of the centres in NHS England that offers it.

Are there any possible disadvantages or risks from taking part?

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. If you are randomised to Partial Ablation, you will then discuss with your doctor whether to have HIFU or IRE. If you are randomised to Radical Treatment, you will then discuss with your doctor whether to have surgery, radiotherapy, or brachytherapy. There are differences between the treatments in terms of what they involve and the side-effects that may occur. These are described in Table 1 and Table 2 above, so that 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.

What are the possible benefits of taking part?

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. Patients in previous trials have found this support reassuring. Further information can be found at:https://www.nihr.ac.uk/patients-carers-and-the-public/i-want-to-take-part-in-a-study.htm / www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

Will my General Practitioner (GP) be informed of my participation?

With your permission, we will let your GP know if you decide to take part in the study.

Will my taking part in the study be kept confidential?

You will be given a unique study number when you agree to take part in the study. In routine communication between your hospital and the University of Oxford Study Office, you will be identified by this study number and your initials. A copy of your signed consent form will be held by the Study Office so that we can confirm that the correct consent procedure has been followed. This will have your name and signature on it.

We will need to use information from you, your medical records, your GP and your hospital records for this research project. We will share your information related to this research project with the following types of organisations; Universities and NHS trusts.
This information will include your initials, NHS number, hospital number, name, contact details and date of birth. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.
Responsible members of the University of Oxford, regulatory authorities and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Information from your medical notes may be transferred to the PART study team at another hospital, if you need to receive your treatment at a different hospital to this one. This will be done securely, as is the case when patients' care is transferred from one NHS Trust to another. It will not be possible for anyone else outside of the study team to identify the results as yours. Responsible members of the University of Oxford and relevant NHS Trusts may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Images of routine samples taken during your biopsies and (if relevant) prostatectomy, may also be sent to the University of Oxford to be reviewed by the PART Pathologist. Images may be taken of histopathology samples, and these images may be used in publications – any images would be anonymous.

Will I be reimbursed for taking part?

It is anticipated that the majority of study patients will be able to receive their treatment at their local centre. If the particular technique of Partial Ablation is not available locally, you will be referred to an appropriate nearby centre, and your travel expenses will be reimbursed (on production of receipts, or mileage allowance provided as appropriate).

What will happen to my data?

UK Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford, based in the United Kingdom as Sponsor of the PART study and the University of Bristol (who are conducting the Information Study) are the joint data controllers and are both responsible for looking after your information and using it properly. All data will be stored and used in compliance with the relevant, current data protection laws (Data Protection Act 2018; United Kingdom General Data Protection Regulation (UK GDPR)). Further information is provided below, and you will need to indicate on the consent forms that you understand this.

We will be using information from you and your medical records in order to undertake this study and will use the minimum personally identifiable information possible. If the study receives additional funding, the University of Oxford intend to check your health status as part of a long-term follow-up (up to 15 years), using NHS Digital or the NHS Central Register (Scotland), and will ask your permission to do this. We will keep research documents with personal information, such as consent forms and radiology scans, for a maximum of fifteen years after the study has finished.

Your local study team will use your name, NHS number and contact details to contact you about the research study. They will keep research documents with personal information, such as consent forms and radiology scans, for a maximum of fifteen years after the study has finished or as per local Trust policy for retention of medical notes. All other identifiable data will be destroyed six months after the end of the study unless you agree to us retaining these for future contact.

If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database but will keep the consent form and your details separate. All contact regarding future research will come from the research team at the University of Oxford in the first instance. Agreeing to be contacted does not oblige you to take part in future research, and you can ask for your contact details to be removed from this register at any time if you wish.

We may disclose your personal data to our third-party service providers to carry out activities specifically for the purpose of this research and as explained in this information sheet. Any third-party service providers are required to take appropriate security measures to protect your personal data in line with University of Oxford policies. We do not allow our third-party service providers to use your personal data for their own purposes, but rather to only process your personal data for specified purposes and in accordance with our instructions.

UK Data protection regulation provides you with control over your personal data and how it is used (further information is available at https://compliance.admin.ox.ac.uk/individual-rights).

When you agree to your information being used in research, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at: https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting part-trial@nds.ox.ac.uk.

What will happen if I want to withdraw from the study?

If you participate in the study, you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Withdrawal from the study will not affect the standard of care you receive. If you would like to withdraw, please contact the Trial Manager at part-trial@nds.ox.ac.uk or inform a member of the PART team and they will discuss your withdrawal options with you – you will need to have your study ID.

What will happen to the results of this study?

We intend to publish the results of the PART study in medical journals, and to present the results at conferences. Please note that it will never be possible to identify you or your individual data

from any report or publication placed in the public domain. A summary of the results will be published on the PART website at the end of the study.

What if I have questions or concerns?

The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact the Chief Investigator, Professor Richard Bryant on 01865 227176 or at part-trial@nds.ox.ac.uk, or you may contact the University of Oxford Research Governance, Ethics & Assurance Team RGEA at RGEA.complaints@admin.ox.ac.uk

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact [Local PALS number] or email [Local PALS email] .

Who is organising and funding the study?

PART is funded by the Health Technology Assessment Programme of the National Institute for Health Research (part of the Department of Health & Social Care). The study is sponsored by and led by the University of Oxford. The NIHR will pay University College London Hospitals NHS Foundation Trust for including you in this study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion South Central - Oxford B Research Ethics Committee.

Further information and contact details

General information about taking part in research can be found here:
www.nhs.uk/Conditions/Clinical-trials/

If you have any concerns or wish to discuss the study further, please contact:

XXX, Research Nurse Tel: Email: Address:	**XXX, Local Principal Investigator** Tel: Email: Address:
PART Trial Manager Email: part-trial@nds.ox.ac.uk Surgical Intervention Trials Unit (SITU) Nuffield Department of Surgical Sciences, University of Oxford	**Chief Investigator** Professor Richard Bryant Tel: 01865 617123 Email: richard.bryant@nds.ox.ac.uk

Botnar Research Centre Nuffield Orthopaedic Centre Windmill Road Oxford OX3 7HE	Nuffield Department of Surgical Sciences, University of Oxford Old Road Campus Research Building Oxford OX3 7DQ
Information Study Lead Dr Daisy Elliott Email: daisy.elliott@bristol.ac.uk Population Health Sciences Bristol Medical School , University of Bristol Canynge Hall 39 Whatley Road Bristol, BS8 2PS	

Thank you for considering taking part.