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A study to investigate using contrast-enhanced ultrasound during focal therapy for prostate cancer

Submission date 21/08/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/08/2025	**Overall study status** Ongoing	
Last Edited 28/08/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
The aim of this study is to assess the use of a tool called contrast-enhanced ultrasound during focal therapy. During the focal therapy operation, the patient's surgeon will use a tool called contrast-enhanced ultrasound to scan the prostate. The contrast-enhanced ultrasound may help the surgeon to see if there is any remaining cancer after the treatment. If there is remaining cancer, they can then deliver further treatment to that cancer straightaway. This study will look at how effective this tool is, how it changes the focal therapy operation, and how long the technique takes to learn. The study will also help determine if it is possible to run further trials in the future studying this tool.

Who can participate?
Patients aged 18 years or above due to undergo focal therapy with HIFU, cryotherapy, or IRE as a first treatment for their prostate cancer.

What does the study involve?
Patients will attend for focal therapy under general anaesthesia as routine. During the focal therapy operation, the surgeon will use contrast-enhanced ultrasound to scan the prostate before and after they have delivered treatment to the cancer. If the surgeon thinks there is remaining cancer, they can then deliver immediate further treatment to that specific area with the patient remaining under the same general anaesthetic.

After the focal therapy operation, patients will undergo PSA testing at 3 and 12 months, an MRI of the prostate at 12 months, and also a needle biopsy of the prostate at 12 months. This will enable us to assess if there is any remaining cancer.

What are the possible benefits and risks of participating?
The main possible benefit is that using contrast-enhanced ultrasound during focal therapy may improve a patient’s cancer treatment, which could in turn lead to future benefits like a lower risk

of needing further treatment. There may be dded risks from the added operating time and delivery of further treatment after contrast-enhanced ultrasound, but these risks are anticipated to be very small.

Where is the study run from?
Imperial College London and Charing Cross Hospital

When is the study starting and how long is it expected to run for?
December 2023 to January 2028

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

Who is the main contact?
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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
339138

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 60474, NIHR304727

Study information

Scientific Title
Imperial Prostate 14 – FOcal therapy using Contrast-enhanced UltraSound

Acronym
IP14-FOCUS

Study objectives
Hypothesis:
The use of intra-operative CEUS, and subsequent delivery of further ablation if there is a suspicion of residual tumour, will lead to a low proportion of patients with clinically-significant prostate cancer diagnosed on biopsy at 12 months post-operatively.

Primary objectives:
1. To estimate the proportion of patients with clinically-significant in-field recurrent cancer at 12 months after focal therapy when using CEUS to guide focal therapy ablative planning intra-operatively

Secondary objectives:
1. To assess recruitment rate to the study and compliance to study interventions
2. To estimate the proportion of patients with clinically-insignificant in-field recurrent cancer at 12 months after focal therapy when using CEUS to guide focal therapy ablative planning intra-operatively
3. To assess how the use of intra-operative CEUS changes the delivery of focal therapy by urologists
4. To assess the additional operative time needed to perform intra-operative CEUS and deliver further ablation
5. To assess the learning curve of urologists to perform and interpret intra-operative CEUS
6. To assess whether urologists can achieve high intervention fidelity for performing and interpreting intra-operative CEUS
7. To assess the safety of using intra-operative CEUS with or without further ablation

8. To assess the short-term functional effects of using intra-operative CEUS with or without further ablation
9. To assess the diagnostic accuracy of MRI, interpreted using dedicated imaging-scoring systems, for detecting clinically-significant recurrent cancer after focal therapy

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 22/08/2025, North West – Haydock REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048117; haydock.rec@hra.nhs.uk), ref: 25/NW/0270

Study design
Interventional non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

Interventions
This study will ask patients who have already agreed to undergo focal therapy at our hospital to take part. These patients will be identified from our prostate multidisciplinary meeting, outpatient clinic lists, or existing focal therapy waiting lists. Patients will be approached by our research team to confirm eligibility through taking a medical history, then discuss the research study and what it involves (including providing a participant information sheet). If patients want to take part, they will sign a consent form to indicate they are giving permission.

Before the date of focal therapy, we will ask patients to complete some questionnaires. These relate to how well their urinary, sexual, and bowel functions are, as well as their general quality of life.

Patients will then attend for their focal therapy procedure as normal. At the start of the procedure, they will be put to sleep under anaesthesia. The surgeon will then perform a contrast-enhanced ultrasound to examine the prostate and find where the cancer is. This involves placing an ultrasound probe in the back passage and injecting a special dye into the veins.

Next, the surgeon will perform focal therapy as they normally would. This includes insertion of a urinary catheter to help protect the water passage. Once this has finished, the surgeon will perform another contrast-enhanced ultrasound. They will now see if there is any part of the cancer still remaining. If there is no cancer remaining, then the operation will finish and the patient will be woken up from anaesthesia. If there is cancer remaining, the surgeon will perform further focal therapy. This will be directed specifically to the area where there was still cancer as seen on the contrast-enhanced ultrasound. Once this is completed, the patient will then be woken up from their anaesthetic.

As would normally happen, the patient is then discharged back home after a few hours in the recovery area. The research team will assess for any problems that occurred with their treatment before the patient leaves the hospital.

Patients will return to hospital to our outpatients department a week or two later to have their urinary catheter removed by a urology nurse as normal. A member of the research team will assess for any problems that occurred with their treatment at this time.

After this, patients will need to have regular checks and tests as we ask all patients who have had focal therapy. This includes having a blood test at 3 months and 12 months after treatment to check their PSA blood test. They will also have a review by the clinical team at these times, either by telephone or face-to-face. As part of these reviews, the patient will be asked about any problems that have arisen that could be related to their treatment. They will also be asked to complete a set of questionnaires. These relate to how well their urinary, sexual, and bowel functions are, as well as their general quality of life.

At 12 months after treatment, patients will also be asked to have an MRI scan of their prostate to see if there is any cancer remaining. This will be followed by a needle biopsy of the prostate, usually under local anaesthetic. Samples of the prostate will be taken and looked at under a microscope to see if there is any cancer remaining. At this point, the trial will end. Patients will return to the 'normal' care pathway for patients who have had focal therapy. This includes further PSA blood tests, clinical reviews, and, if required, further MRI scans and prostate biopsy.

We want to ask up to 118 patients to take part in our study. This number will help us to answer questions about the effect of using contrast-enhanced ultrasound. These answers will help design a larger study to further investigate its role.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Proportion of patients with clinically-significant prostate cancer within the treatment zone on biopsy at 12 months, defined as cancer that is grade group 2 or higher, in those patients who undergo prostate biopsy. Timepoint: 12 months post-operatively

Secondary outcome measures
1. Recruitment rate: the percentage of approached patients who consent to participate per month. Timepoint: baseline
2. Biopsy rate: the number of patients who agree and disagree to undergo prostate biopsy at 12

months, with reasons if disagreement. Timepoint: 12 months post-operatively
3. Proportion of patients with clinically-insignificant prostate cancer within the treatment zone on biopsy at 12 months, defined as cancer that is grade group 1, in those patients having a biopsy. Timepoint: 12 months post-operatively
4. Proportion determined by the treating urologist that the CEUS performed after focal therapy is negative, equivocal, or suspicious for residual tumour. Timepoint: day 0 (intra-operatively)
5. Proportion undergoing further ablation by the treating urologist after performing intra-operative CEUS. Timepoint: day 0 (intra-operatively)
6. The time in minutes required to set up and perform CEUS intra-operatively pre-focal therapy. Timepoint: day 0 (intra-operatively)
7. The time in minutes required to set up and perform CEUS intra-operatively post-focal therapy. Timepoint: day 0 (intra-operatively)
8. The time in minutes required to deliver further ablation, if performed. Timepoint: day 0 (intra-operatively)
9. Temporal changes in time required to set up and perform intra-operative CEUS, measured on a per-urologist basis. Timepoint: day 0 (intra-operatively)
10. Agreement over CEUS image interpretation score between the treating urologist and an expert user, measured on a per-urologist basis. Timepoint: day 0 (intra-operatively)
11. Proportion of individual CEUS steps performed to completion, assessed by an expert user. Timepoint: day 0 (intra-operatively)
12. Proportion of individual CEUS steps performed to optimal quality, assessed by an expert user. Timepoint: day 0 (intra-operatively)
13. Proportion of CEUS images with suspicion score concordant with a score given by an expert user. Timepoint: day 0 (intra-operatively)
14. Proportion of patients experiencing adverse events. Timepoint: Measured on day 0, then 1-2 weeks, 3 months, and 12 months post-operatively
15. Questionnaire scores pertaining to urinary, sexual, and bowel function and health-related quality-of-life, measured using validated questionnaires. Timepoint: Measured at baseline, then 3 months and 12 months post-operatively
16. Concordance between MRI interpretation scores (index test) and targeted biopsies of the treatment zone (reference test) in detecting clinically-significant residual cancer, defined as grade group 2 cancer or higher (target condition), in those patients who undergo prostate biopsy. Timepoint: 12 months post-operatively

Overall study start date
01/12/2023

Completion date
01/01/2028

Eligibility

Key inclusion criteria
1. Age 18 years or above (no upper limit)
2. Patients with localised prostate cancer defined as a T-stage of T1-T3a and PSA < = 20 ng/mL, either newly-diagnosed or on active surveillance
3. Patients suitable for and booked to undergo focal HIFU, cryotherapy, or irreversible electroporation for localised prostate cancer, with or without neoadjuvant androgen-deprivation therapy. ‘Focal’ is defined as ablation delivered to a maximum of three quarters of the prostate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
118

Key exclusion criteria
1. Unable to give consent
2. Patients undergoing surgery for symptoms of bladder outlet obstruction, for example transurethral resection of the prostate, at time of focal therapy
3. Any previous local therapy for prostate cancer, including radiotherapy (external-beam radiotherapy or brachytherapy), radical prostatectomy, and ablative treatments
4. Any surgery for benign prostatic obstruction within the previous 6 months
5. Any contraindication to receiving the sulphur hexafluoride ultrasound contrast agent including evolving or ongoing myocardial infarction, typical angina at rest, significant worsening of cardiac symptoms, recent coronary artery intervention, acute cardiac failure, class III/IV cardiac failure, severe cardiac arrhythmias, right-to-left shunts, severe pulmonary hypertension (pulmonary artery pressure > 90 mmHg), uncontrolled systemic hypertension, and adult respiratory distress syndrome
6. Unable to undergo MRI, including intravenous administration of gadolinium-based contrast

Date of first enrolment
01/11/2025

Date of final enrolment
01/01/2027

Locations

Countries of recruitment
United Kingdom

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
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Sponsor information

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University/education

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ROR
https://ror.org/041kmwe10

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request. The publication will be in line with ICMJE requirements and therefore explicitly state the researchers' conditions on: data types; additional available documentation; window of availability (dates indicating opening and closure of access); eligibility of requests; types of analysis permitted; method of access. The researchers will post the data-sharing opportunity on their university websites. They will also take queries from interested third parties to assist and guide them to the opportunity. All subsequent publications of primary and secondary outcomes will be compliant with the NIHR Open Access Policy (https://www.nihr.ac.uk/documents/nihr-open-access-policy/12251). During the period of funding, the datasets will be collected and completed in the manner described above. The researchers anticipate opening up access beyond the existing research group within 24 months after funding is complete. There will be a lock-out period to enable the key outcomes of the studies to report first after which data access will be through application to the study group. Shah will act as the data custodian on behalf of Imperial College London and hold overall responsibility for data management. Shah will be responsible for data security and quality assurance.

IPD sharing plan summary
Available on request