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A study comparing the effect of apalutamide treatment before focal therapy with focal therapy alone in men with prostate cancer that has not spread beyond the prostate

Submission date
17/12/2025

Recruitment status
Not yet recruiting

Registration date
13/01/2026

Overall study status
Ongoing

Last Edited
10/04/2026

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Men diagnosed with significant prostate cancer, confined to the prostate, are increasingly undergoing focal therapy rather than traditional radical treatments such as whole-gland surgery or radiotherapy. Focal therapy is a targeted treatment for prostate cancer and thus it not only minimises damage to surrounding tissue, it also results in lower side effects than traditional treatments. Just like any cancer treatment, some patients' cancer will return (recurrence). A potential solution would be to use drugs prior to the focal therapy (neoadjuvant treatment), which would maintain the low side effects from treatment whilst improving its efficacy and reducing the recurrence rate.
Apalutamide is a hormone therapy that targets the testosterone pathway and has been shown to shrink cancers. We believe that using apalutamide before focal therapy may improve outcomes further for men who receive focal therapy. There have, however, been no randomised control trials (RCTs) assessing the improvement of cancer control outcomes in patients twhoundergo focal therapy alone versus focal therapy with apalutamide.
To answer this question, we have designed a randomised control trial with an embedded pilot study aimed at comparing the cancer control outcomes of neoadjuvant apalutamide followed by focal therapy with focal therapy alone.

Who can participate?
Men aged 18 years and over with localised prostate cancer who are due to undergo focal therapy as part of their care

What does the study involve?
Participants will be randomly allocated to one of two groups.
Control group: Focal therapy alone as per tumour characteristics.
Intervention group: Neoadjuvant apalutamide 240 mg orally once daily for 3 months (90 days) followed by focal therapy (as per control group).
During the treatment period,questionnaires will be completed. Following focal therapy,

participants will be followed up 3-monthly for the first year and then 6-monthly from thereon. All participants will undergo an additional prostate biopsy at 6-12 months following their focal therapy treatment. For the pilot study, all participants will be followed up for at least 12 months. If the study proceeds into the main study, all participants will be followed up for 5 years or until the end of the study (whichever occurs first). Questionnaires will continue to be completed throughout the follow-up period.

What are the possible benefits and risks of participating?
We will aim to carry out the screening and consent visit during one of the routine standard clinic appointments (where possible) as there are often a number of visits to hospital for men diagnosed with prostate cancer before treatment is started. They can also agree to telephone or email consultations during the follow-up period, provided they undergo PSA blood tests and provide the Patient Reported Outcome Measure questionnaires at the appropriate timepoints. PSA tests may be completed at GPs or local hospitals where this is preferred for the participant and data can be obtained by the research team. The follow-up visits reflect standard care follow-up regimens to minimise the burden of visits.
Focal therapy may cause side effects such as urinary problems, rectal problems and erectile dysfunction. This will be explained very clearly to the men wishing to participate. They will be told that the impact on local sexual, urinary and rectal function is associated with the focal therapy and may occur regardless of whether they choose to participate in the study if they proceed with focal therapy.
Apalutamide has known side effects such as tiredness, decreased libido, weight gain, fracture, breast swelling and tenderness in a minority of men, which is explained in the patient information sheet. Some men taking Apalutamide have also been shown to have an increased risk of ischemic heart disease, ischemic cerebrovascular disorders, hypothyroidism and seizures. These will be closely monitored. Side effects noted with long term use of hormone therapy (in particular, bone thinning) is not anticipated as participants are only due to take apalutamide for 90 days.
We have attempted to ensure that there is a balance between obtaining the necessary information we need to measure the impact of each treatment on quality of life and the burden of filling in questionnaires. From our previous experience in trials, we have found that the majority of men appreciate the opportunity to fill in these questionnaires as they often find it beneficial to themselves to show the objective impact through such questionnaires following treatment.
An MRI scan is painless and does not involve any radiation. Before these scans, contrast dye may be injected with a needle into one of the veins. The injection of contrast medium may cause some discomfort and bruising. Although reactions to contrast dye are rare, there is a risk of possible serious allergic reactions or kidney damage in some individuals who receive contrast dye. The most common side effects are hives and nausea. Participants may undergo additional imaging procedures as part of standard of care during diagnosis and if there is suspected disease progression. These could include CTs, PET-CTs, radioisotope bone scans and whole body MRI scans. The risks associated with these procedures are not related to the trial as they would be completed routinely if not taking part in the trial.

Where is the study run from?
Imperial College Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
May 2026 to July 2029

Who is funding the study?
Janssen Cilag Ltd (who manufacture apalutamide) are funding the initial pilot stage of the study and will be supplying apalutamide free of charge

Who is the main contact?
Tayla Perreau (Clinical Trial Manager), apollo.study@imperial.ac.uk

Plain English summary under review with external organisation

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Additional identifiers

Integrated Research Application System (IRAS)
1013250

Protocol serial number
172928

Study information

Scientific Title
IP17- Apalutamide prior to Prostate ablation Of focal Lesions in patients with LOcalised prostate cancer

Acronym
IP17-APOLLO

Study objectives
Primary objectives:
Pilot Phase:
To determine patient acceptance of randomisation, measured using rates of accrual and compliance

Main Phase:
To evaluate progression-free survival (PFS) rates of focal therapy alone compared to focal therapy with 3 months of neo-adjuvant Apalutamide in the treatment of non-metastatic clinically significant prostate cancer

Secondary objectives:
Pilot phase:
1. To determine the pathological response rate as defined by any Gleason 3+4 or greater cancer on 6–12-month post- treatment protocol mandated control biopsies after the initial focal therapy session
2. To determine the pathological effect from 3 months of apalutamide, determined on pre-focal therapy biopsies of the prostate
3. To determine the genitourinary and rectal side-effects and quality of life metrics measured using validated patient-reported outcome measures (PROMs) and adverse events

Main phase:
1. Cost-effectiveness of apalutamide plus FT versus FT alone
2. Determine the histological, biochemical and oncological disease control for patients undergoing focal therapy alone or focal therapy with neoadjuvant apalutamide

3. Determine the adverse events and functional outcomes after focal therapy alone or focal therapy with neo/adjuvant treatments
4. Development of an imaging repository

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/02/2026, Wales Research Ethics Committee 2 (Health and Care Research Wales Floor 4 Crown Building Cathays Park, Cardiff, CF10 3NQ, United Kingdom; -; Wales.REC2@wales.nhs.uk), ref: 26/WA/0013

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Localised prostate cancer

Interventions
Two-arm, adaptive randomised control trial (RCT) with an internal pilot and blinded interim analysis to compare PFS following focal therapy alone versus 3 months of neoadjuvant apalutamide and focal therapy.

Participants will be randomised using Sealed Envelope on a 1:1 basis into one of two arms as per below.

Control arm (Arm 1):
Focal therapy alone (high intensity focused ultrasound [HIFU], irreversible electroporation [IRE] or cryotherapy) as per tumour characteristics.

Intervention arm (Arm 2):
Neoadjuvant apalutamide 240 mg orally once daily for 3 months (90 days) followed by focal therapy (as per control arm).
During the treatment period, Patient Reported Outcome Measure (PROM) questionnaires will be completed. Following focal therapy, participants will be followed up 3-monthly for the first year and then 6-monthly from thereon. All participants will undergo an additional prostate biopsy at 6-12 months following their focal therapy treatment. For the pilot study, all participants will be followed up for at least 12 months. If the study proceeds into the main study, all participants will be followed up for 5 years or until the end of the study (whichever occurs first). PROMs will continue to be collected throughout the follow-up period.

Intervention Type
Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)
Apalutamide

Primary outcome(s)
Pilot Study:
1. Recruitment rate per centre per month measured at the end of each month until the final patient is recruited.
2. Acceptance of randomisation (rate-per-month per-centre average) and compliance to allocated arm measured at time of consent (acceptance to randomisation) and at time to treatment (compliance)

Main Study:
Progression-free survival (PFS), defined as the time from randomisation to the first incidence of further focal therapy or salvage whole-gland treatments (radiotherapy or surgery) or prostate cancer metastases (radiologically confirmed) or prostate cancer-specific mortality. Measured at time of progression or failure judged clinically or a maximum of 5 years follow-up after focal therapy.

Should the study continue to the main phase, all patients (including those enrolled during the pilot) will continue follow-up over a total of 60 months and the endpoint will be assessed at the end of this period.

Key secondary outcome(s))
Pilot Study:
1. Pathological response rate as defined by any Gleason 3+4 or greater cancer on 6–12-month post- treatment protocol mandated control biopsies after the initial focal therapy session.
2. Pathological effect from 3 months of apalutamide determined on pre-focal therapy biopsies of the prostate
3. Genitourinary and rectal side-effects and quality of life metrics measured using validated patient-reported outcome measures (PROMs) and adverse events at time of consultation for study, after consent and after treatment at 6–12-month follow-up

Main Study:
Disease control:
1. Rate of positive biopsy for any cancer and significant cancer is measured using histology on biopsy prior to focal therapy (treated and untreated side) at baseline and after 3 months of neoadjuvant Apalutamide
2. Rate of positive biopsy for any cancer and significant cancer is measured using histology on biopsy following focal therapy (treated and untreated side) at baseline and annually throughout the 5-year follow-up period
3. Rate of second or third focal therapy sessions (in-field or out-of-field) is measured using treatment records at baseline and annually throughout the 5-year follow-up period
4. Rate of radiotherapy as salvage therapy following focal therapy is measured using treatment records at baseline and annually throughout the 5-year follow-up period
5. Rate of prostatectomy as salvage therapy following focal therapy is measured using treatment records at baseline and annually throughout the 5-year follow-up period
6. Rate of systemic therapy as salvage therapy following focal therapy is measured using treatment records at baseline and annually throughout the 5-year follow-up period
7. Metastases-free survival is measured using imaging and clinical records at baseline and

annually throughout the 5-year follow-up period
8. Prostate cancer-specific mortality is measured using death certificates and clinical records at baseline and annually throughout the 5-year follow-up period
9. All-cause mortality is measured using death certificates and clinical records at baseline and annually throughout the 5-year follow-up period
10. Long-term health outcomes are measured using clinical records and patient-reported outcome measures at baseline and annually throughout the 5-year follow-up period

Adverse events and functional outcomes :
11. Rate of cystoscopic interventions following treatment is measured using procedure records at baseline and annually throughout the 5-year follow-up period
12. Rate of implant insertion for treatment of incontinence and erectile dysfunction is measured using procedure records at baseline and annually throughout the 5-year follow-up period
13. Rate of medication and/or pump devices used for erectile dysfunction following treatment is measured using prescription records at baseline and annually throughout the 5-year follow-up period
14. Rate of endoscopic investigations of the lower bowel following treatment is measured using procedure records at baseline and annually throughout the 5-year follow-up period
15. Rate of pad-use and quantity per day for urinary incontinence following treatment is measured using patient diaries at baseline and annually throughout the 5-year follow-up period
16. Rate of pad-use and quantity per day for faecal incontinence following treatment is measured using patient diaries at baseline and annually throughout the 5-year follow-up period
17. Adverse event rates and complications are measured using CTCAE v4.0 at baseline and annually throughout the 5-year follow-up period
18. Genito-urinary and rectal side-effects are measured using EQ-5D-5L, International Index of Erectile Function-15, International Consultation on Incontinence Questionnaire (ICIQ), EPIC-26, International Prostate Symptom Score and CTCAE v4.0 bowel domain at baseline and annually throughout the 5-year follow-up period including evaluation of return to baseline function and clinically relevant decreases in PROMs scores

Qualitative:
19. Impact on participants' overall health-related quality-of-life is measured using EQ-5D-5L and EPIC-26 at baseline and annually throughout the 5-year follow-up period

Imaging and Pathology:
20. Accuracy and variability of multi-parametric MRI in detecting disease are measured using mpMRI compared to histology outcomes on biopsy at baseline and annually throughout the 5-year follow-up period

21. Toxicities are measured using CTCAE v4.0 at baseline and annually throughout the 5-year follow-up period
22. Progression or failure-free survival is measured using clinical records and imaging at baseline and annually throughout the 5-year follow-up period

Completion date
01/07/2029

Eligibility

Key inclusion criteria

1. Age >/=18 years with no upper limit
2. PSA ≤20 ng/ml
3. MRI stage <=T3aN0M0. Broad capsular contact is permitted, macroscopic disease outside capsule is not.*
4. Overall Gleason ≤4+3 and maximal Gleason 4+4 within the targeted cores to allow for targeted biopsy artefact. Low volume (<4 mm) of Gleason 3+3 or 3+4 will be permitted outside of the lesion being treated.
5. Pathology should be concordant with a lesion on prostate MRI.
6. Fit for a general anaesthetic.
7. Can give informed consent

*Patients must have undergone a diagnostic pre-biopsy MRI compliant with national uro-radiology consensus guidelines. Dynamic contrast enhancement using gadolinium is not required at diagnostic stage but will be required during follow-up.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
120 years

Sex
Male

Total final enrolment
0

Key exclusion criteria
1. Locally advanced disease (macroscopic T3a or T3b+) that is not suitable for focal therapy
2. Life expectancy of less than 5 years
3. Unable to undergo a multiparametric 1.5 or 3T MRI
4. Previous treatment for prostate cancer, including hormonal therapy, radiotherapy or surgery (the use of 5-alpha reductase inhibitors is not an exclusion criterion)
5. History of seizures or other predisposing factors, including underlying brain injury, recent stroke (within 1 year), primary brain tumours or brain metastases
6. No contraindication to apalutamide*

Any of the following within 12 months prior to first dose of study drug: severe or unstable angina, myocardial infarction, symptomatic congestive heart failure, arterial or venous thromboembolic events (example, pulmonary embolism, cerebrovascular accident including transient ischemic attacks), or clinically significant ventricular arrhythmias or New York Heart Association Class II to IV heart disease; uncomplicated deep vein thrombosis is not considered exclusionary. Hypersensitivity to anti-androgen therapy.

Date of first enrolment

08/05/2026

Date of final enrolment
01/03/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Charing Cross Hospital
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Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type

Funder Name
Janssen Cilag Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date