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A randomised phase 3 trial evaluating the role of finasteride in increasing compliance with active surveillance, in men with a new diagnosis of low and intermediate risk prostate cancer, when compared with usual care.

Submission date	**Recruitment status**	[X] Prospectively registered
27/07/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/08/2021	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/07/2026	Cancer	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Prostate cancer is cancer that occurs in the prostate. The prostate is a small walnut-shaped gland in males that produces the seminal fluid that nourishes and transports sperm.

Prostate cancer is the most common cancer in men. Many prostate cancers are not lethal and can be safely managed by observation (Active Surveillance). Over time, more than half of the men who choose observation receive radical surgery or radiotherapy. Both treatments produce side effects and may be unnecessary. Most men opt for treatment because of their rising PSA (prostate blood test) levels. This usually reflects aging of the prostate, rather than advancing cancer.

We aim to improve what is offered, so more men remain on observation. We believe a drug called finasteride may help. Finasteride slows prostate growth and reduces PSA levels. Finasteride has few side effects and has been shown to reduce the risk of a man developing prostate cancer. We predict that finasteride will reduce the number of men receiving radical treatment from 20% to 10% at 4 years.

Who can participate?

Men aged 50 – 75 years who are receiving observation for low/intermediate-risk prostate cancer

What does the study involve?

We will randomise up to 304 men receiving observation for low/intermediate risk prostate cancer to either finasteride or usual care. All men will receive Active Surveillance; including PSA testing (3 monthly year 1 and 6 monthly years 2/3) and MRI scanning (at year 1 and 3). Prostate biopsies will be used for men with changing MRI scans and at year 3.

What are the possible benefits and risks of participating?

Benefits: Participants may benefit from the medication used

Risks: Potential participants will be informed of all the possible risks associated with taking finasteride, and they will also be documented in the Patient Information Leaflet (PIS). Common side effects: Impotence, Decreased libido, Decreased volume of ejaculate

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

When is the study starting and how long is it expected to run for?
April 2021 to March 2029

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

Who is the main contact?
1. Prof Jim Catto, j.catto@sheffield.ac.uk
2. Finesse study team, cptu-finesse@qmul.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-finasteride-and-active-surveillance-for-newly-diagnosed-prostate-cancer

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2021-004004-17

Integrated Research Application System (IRAS)
1004290

Protocol serial number
STH21032

Study information

Scientific Title
FINasteride Evaluation in active Surveillance for low and intermediate-risk prostate cancer

Acronym
FINESSE

Study objectives
We aim to test if the drug finasteride can increase the adherence of men to surveillance programs and reduce radical treatment rates. Many men opt for treatment because of their rising PSA levels, which usually reflects non-cancerous enlargement of the prostate, rather than progressive/advancing cancer. We hypothesise, that the addition of finasteride to usual care, in

men receiving active surveillance for prostate cancer, will increase adherence in surveillance. In turn, this will reduce the rates of radical and palliative treatment. We hypothesise, this will occur through reduced PSA values (in absolute terms) and reductions in benign PSA fluctuation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/12/2021, South Central – Oxford C (Oxfordshire Research Ethics Committee C) (Health Research Authority (Bristol), Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN; +44 (0)207 104 8226; oxfordc.rec@hra.nhs.uk), ref: 21/SC/0349

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Men with a new diagnosis of low- and intermediate-risk prostate cancer

Interventions
Current interventions as of 24/06/2025:
For men randomised within 6 months of their diagnosis date, it is likely their standard active surveillance assessments will align with their FINESSE Trial follow-up appointments as indicated below.

Year One: Once randomised, participants will continue to attend routine active surveillance appointments every three months (+/- 14 days). FINESSE appointments will take place at the same time and, where applicable, a prescription will be issued, and IMP dispensed on a 3-month basis. As is standard practice for men on active surveillance, blood samples for PSA testing will be taken at months 3, 6, 9 & 12, a repeat MRI scan will be carried out at month 12, and, where it is local practice, a digital rectal examination (DRE) will be given.

The results of all these examinations will be captured in the FINESSE EDC, and copies of the MRI scan and report will be transferred to the Lead Radiologist by the LCO for review. Full details regarding MRI scans, including reporting protocols, will be documented in the FINESSE Study Radiology Manual.

Year Two: Whilst the frequency of routine active surveillance and blood samples for PSA testing will drop to 6 monthly, FINESSE study appointments will continue to be scheduled on a 3-monthly basis (+/-14 days) to enable men randomised to the active arm of the trial to collect their prescription and IMP. This means participants will be required to attend two additional visits at months 15 and 21 during this period. Whilst these visits may be conducted virtually by telephone or video call, if necessary, and IMP dispatched by post, participants in the finasteride arm must ensure they return their remaining IMP for a pill count.

Participants may undergo a DRE at month 24 as per local practice. The results of this examination, if conducted, will be recorded on the trial EDC, but it is not mandatory. Where applicable, dispensing of the IMP will stop at the end of year two.

Years three to five inclusive: Participants will continue to attend routine active surveillance appointments on a 6-month basis, and all FINESSE study appointments will take place at the same time. A year 3 MRI scan, followed by a discussion of the findings in clinic, and a subsequent prostate re-biopsy where indicated by the MRI scan, are strongly recommended, where the assessment(s) can be arranged locally, as part of usual care.
Where conducted, the LCO will be responsible for transferring copies of the year 3 MRI scan and report to the Lead Radiologist and recording the results of the investigations in the trial EDC. The site may also be asked to send corresponding year 3 biopsy slides to the Lead Pathologist. Full details can be found in the FINESSE Study Pathology Manual.

However, for many participants, this will not be the case. E.g. for a man diagnosed 24 months prior to randomisation, their year three standard active surveillance will correspond with their first year of FINESSE study follow-up.

Nevertheless, these men will be seen on a three-month basis for years one and two of the trial, to enable men randomised to the active arm of the trial to collect their prescription and IMP. This means participants will be required to attend up to four additional visits at months 3, 9, 15 and 21 during this period. Whilst these visits may be conducted virtually by telephone or video call, if necessary, and IMP dispatched by post if sites have the capacity and systems in place, participants in the finasteride arm must ensure they return their remaining IMP for a pill count.

Follow up:
After trial completion, annual surveillance in the community (by their GP) will be recommended for men with stable prostate cancer. In men with fluctuating or concerning parameters, surveillance by their referring urologist will be recommended.

Sample size: It is estimated that finasteride will reduce the rate of cessation from AS adherence from 40% to 22.5% after an average of 3 years of follow-up, based on similar results from the ENACT trial. The calculation accounts for the initial low recruitment rate, i.e. that accrual is weighted towards the end of the recruitment period. This is a hazard ratio of 0.5. Under that scenario the sample size is 304 men (or 152 per arm), based on a time to event analysis with 90% power to reject H0: Hazard Ratio = 1 i.e. the detection of a significant difference in the rate of cessation from AS adherence between arms by use of a two-sided log-rank test with alpha=0.05. However, there are many unknowns within this trial, including tumour-risk populations, progression rates, men's views of AS, and new screening randomised controlled trials recruiting. Therefore, all findings will be valuable, and providing a minimum of 200 participants is reached by the 30th of September 2025, the study will not be terminated early.

Previous interventions:
FINESSE is a multicentre, open-label, prospective, two-armed randomised controlled CTIMP, to test the superiority of finasteride and active surveillance over- active surveillance alone, in men with newly diagnosed low/intermediate risk localised prostate cancer.

We will randomise (1:1), 550 patients to Active Surveillance with or without once daily finasteride, (5mg). Patients will receive finasteride for 2 years and will be followed up for an average of 4 years. Active surveillance will include PSA, re-biopsy and mpMRI as per usual NHS care. The primary outcome is adherence with Active Surveillance in both arms.

• There are no placebo treatments for the following reasons: The PSA levels in men treated with finasteride will almost halve. Since it is necessary to monitor PSA (for AS) this would unblind both arms unless clinicians and patients were blinded to the PSA results.
• Blinding PSA data would be impractical, since men may actively seek PSA tests outside the study.
• It is ethical that control patients experiencing any side effects, e.g., erectile dysfunction, ejaculatory problems, or a rash, know they are independent of the treatment.
• Participants unaware they are taking finasteride may opt for radical treatment earlier. This is a pragmatic trial designed to see whether knowing that they are being treated and that the treatment is having a positive impact on PSA levels would reassure men and enable them to continue with active surveillance for longer, rather than seeking radical treatment even though their disease may not have progressed.
• The prohibitive costs & logistics associated with placebo-controlled trials

Randomisation:
A web-based randomisation system will be designed, using the bespoke KCTU randomisation system. The randomisation system will be created in collaboration with the trial analyst/s and the CI and maintained by the King's Clinical Trials Unit for the duration of the project. It will be hosted on a dedicated server within KCL.

Finasteride:
Patients randomised to the treatment arm will receive once a day 5mg finasteride for two years in addition to Active Surveillance. Finasteride dispensing will be performed by the hospital pharmacy, with 3 monthly dispensing, and any visits required outside of routine AS appointments (for PSA testing or mpMRI) will have travel expenses reimbursed. Men may remain on finasteride, after 2 years, if they choose to. Pharmacovigilance reporting will continue for one month post the last finasteride treatment. Any side effects or adverse events (AEs) related to the study drug will be reported to the research nurse at study visits, and reasons for withdrawal from Finasteride will be captured. A safety analysis of the study drug will be completed at the end of the study, with yearly safety updates (Development Safety Update Reports - DSURs) to the MHRA.

Active Surveillance:
Men will be monitored using a combination of:
• Digital Rectal examination (DRE) and PSA measurement will be performed 3 monthly in year 1, 6 monthly in all subsequent years within this trial (2-5 years)
• MRI at 12 months and 36 months after diagnosis. Further MRIs will be indicated when PSA kinetics breach prespecified thresholds (Doubling Time (DT) < 3 years), or when clinical examination suggests progressive disease.
• Prostate biopsy will be performed in men with clinical, biochemical progression (PSA DT <3 years) or radiological progression (increasing disease burden on MRI) or at 36 months after diagnosis (after the 36 month MRI).

Follow up:
After trial completion, we will recommend annual surveillance in the community (by their GP) for men with stable prostate cancer. In men with fluctuating or concerning parameters, we will recommend surveillance by their referring urologist.

Sample size: We estimate finasteride will reduce radical treatment rates by 50% (from 20% to 10%) after an average of 4 years follow-up. The sample size is based on waning 90% power to

detect a significant difference (using a two-sided log-rank test with alpha=0.05) assuming that 50% of control patients will progress (or be treated) during follow-up and that the hazard ratio is 0.65. The exact number needed is 271 per arm.

Intervention Type
Drug

Phase
Phase III

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

Primary outcome(s)
Current primary outcome measure as of 24/06/2025:
Adherence to active surveillance in men with low or intermediate prostate cancer with and without 2 years of finasteride during follow-up of between 2 and 5 years from randomisation. Adherence is defined as men who have received neither radical nor palliative treatment, and have remained progression-free under surveillance, at each time point.

Previous primary outcome measure:
Adherence with Active Surveillance at 2 and 5 years after diagnosis. Adherence is defined as the absence of a change in treatment to radical therapy or treatment of advanced disease, measured using patient records.

Key secondary outcome(s)
Current secondary outcome measures as of 24/06/2025:
1. Time until cessation of AS due to:
1.1. ADT and/or chemotherapy initiation
1.2. Radical Prostatectomy
1.3. Radical Radiotherapy initiation
1.4. Other treatment, including watchful waiting
1.5. Death from prostate cancer
2. Participant's death from prostate cancer
3. Changes in MRI appearances of the prostate over time in men with/without finasteride measured using MRI scan results at baseline, 12 and 36 months study follow-up timepoints
4. Views of patients and healthcare professionals regarding the use of finasteride within active surveillance for this disease were measured using semi-structured one-to-one interviews led by a trained interviewer, with selected individuals during the follow-up phase (months 36 to 48 inclusive).
5. The rate of intervention for symptoms related to benign prostate enlargement (defined as the use of oral medication (such as alpha blocker, PDE5 inhibitor or anti-cholinergic) or endoscopic prostate surgery (such as TURP, Urolift, Green light laser TURP, steam treatment, HOLEP or other)), measured using patient self-reporting
6. Overall (all-cause) mortality measured using data collected on death in the electronic case report forms (eCRF) completed by sites

Previous secondary outcome measures:
1. Quality of life measured using EQ-5D-5L, EORTC QLQ C30, EPIC, EORTC QLQ FA12, Memorial Anxiety Scale PC, DASS 21, completed at 3, 6, 12, 18, 24, 36, 48 and 60 months
2. Compliance with and tolerability of finasteride measured in the Finasteride arm by summary

of tablets returned count (median and minimum, maximum) at the end of treatment
3. Satisfaction and quality of decision-making measured using Decisional Conflict Scale, Subjective decision quality scale, Decisional regret scale at 3, 6, 12, 18, 24, 36, 48 and 60
4. Side effects of finasteride measured using the count of adverse events in Finasteride arm. All adverse events occurring during the 3-5 year follow-up of the study
5. Prostate cancer progression measured using mpmpMRI stage, Increase in biopsy grade, Using prostatectomy histology, PSA defined progression, Clinical stage progression (using DRE), Development of radiologically proven metastases, Death from prostate cancer during the 3-5 year follow-up of the study
6. Changes in mpmpMRI appearances of the prostate over time measured using mpmpMRI scan results at baseline, 12 and 36 months
7. Views of patients, partners, para-medical and clinical staff regarding the use of finasteride within active surveillance for this disease measured using semi-structured one-to-one interviews with selected individuals during the follow-up phase (months 45-54 inclusive)
8. Rate of intervention for symptoms related to benign prostate enlargement (defined as the use or oral medication (such as alpha blocker, PDE5 inhibitor or anti-cholinergic) or endoscopic prostate surgery (such as TURP, Urolift, Green light laser TURP, steam treatment, HOLEP or other) measured using patient records during the 3-5 year follow-up of the study

Completion date
31/03/2029

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 24/06/2024:
1. Male participants:
1.1. Aged 50 to 75 years
1.2. With an estimated life expectancy of 10 years or more
1.3. Those who have opted for Active Surveillance as their preferred prostate cancer therapy.
2. Willing and able to provide written informed consent or, if appropriate, have an acceptable individual capable of giving consent on their behalf
3. Fit enough and suitable for radical treatment
4. Eastern Oncology Performance (ECOG) status ≤ 1
5. Histopathological diagnosis of low or intermediate risk adenocarcinoma of the prostate in the last 24 months (from the date of histology to the date of the patient's randomisation)
6. Gleason grade group ≤ 2 (i.e. Gleason grade ≤ 3+4=7)
7. Radiological stage ≤T2c cN0 cM0 as defined by MRI imaging within the last 12 months (from the date of the MRI scan to the date of the patient's randomisation). A copy of the MRI scan and report confirming eligibility will be required. In this study, MX will be treated as M0, and NX will be treated as N0.
8. PSA ≤20ng/ml. The result must be within 3 months of the date of the patient's randomisation
9. PSA Density ≤0.2 ng/ml. NB: For the PSA density result to be valid, the PSA test from which the serum PSA level value is taken must be dated within the last three months, and the MRI scan from which the prostate volume is taken must be dated within the last 12 months
10. Biopsy criteria (route can be trans-rectal or trans-perineal, but must have been within the last 24 months of the patient's randomisation date)

Previous participant inclusion criteria as of 12/12/2023 to 24/06/2025:
1. Male participants:
1.1. Aged 50 to 75 years old

1.2. With an estimated life expectancy of 10 years or more
1.3. Have opted for Active Surveillance as their preferred prostate cancer therapy
2. Willing and able to provide written informed consent or if appropriate, have an acceptable individual capable of giving consent on their behalf
3. Fit enough and suitable for radical treatment
4. Eastern Oncology Performance (ECOG) status ≤ 1 (See figure one below)
5. Histopathological diagnosis of low or intermediate-risk adenocarcinoma of the prostate in the last 24 months (from the date of histology to the date of the patient's randomisation)
6. Gleason grade group ≤ 2 (i.e. Gleason grade ≤ 3+4=7)
7. Radiological stage ≤T2c cN0 cM0 as defined by bpMRI/mpMRI imaging within the last 12 months (from the date of the bpMRI/mpMRI scan to the date of the patient's randomisation). A copy of the bpMRI/mpMRI scan, and report confirming eligibility will be required. In this study, MX will be treated as M0, and NX will be treated as N0.
8. PSA ≤20ng/ml. The result must be within 3 months of the date of the patient's randomisation.
9. PSA Density ≤0.2 ng/ml. The result must be within 3 months of the date of the patient's randomisation
10. Biopsy criteria (route can be trans-rectal or trans-perineal, but must have been within the last 24 months of the patient's randomisation date) regardless of biopsy strategy:
10.1. Maximum cancer core length is ≤ 10mm
10.2. ≤3cores involved with cancer

Previous participant inclusion criteria as of 16/11/2021 to 12/12/2023:
1. Male subjects aged 50 to 75 years with an estimated life expectancy of 10 years or more, who have opted for Active Surveillance as their preferred prostate cancer therapy
2. Willing and able to provide written informed consent or if appropriate, have an acceptable individual capable of giving consent on their behalf
3. Fit enough and suitable for radical treatment
4. Eastern Oncology Performance (ECOG) status ≤ 1 (See figure one below)
5. Histopathological diagnosis of low or intermediate-risk adenocarcinoma of the prostate in the last 6 months (from the date of histology to the date of the patient's eligibility assessment)
6. Gleason grade group ≤ 2 (i.e., Gleason grade ≤ 3+4=7)
7. Radiological stage ≤T2b cN0 cM0 as defined by mpMRI imaging within the last 6 months.
8. PSA ≤20 ng/ml
9. PSA Density ≤0.2
10. Biopsy criteria (route can be trans-rectal or trans-perineal, but must have been within the last 6 months of registration):
10.1. If targeted biopsy then the maximum cancer core length is ≤10 mm
10.2. If targeted and systematic sampling biopsy then the maximum cancer core length should be ≤ 10 mm, and ≤2 or ≤15% of non-targeted cores involved with cancer.
10.3. If non-targeted biopsy (i.e., USS template or sampling irrespective of lesions) then maximum cancer core length is ≤ 10mm AND ≤3 or ≤20% of total number of cores involved with cancer

Previous participant inclusion criteria:
1. Men aged 50 – 75 years with low or intermediate-risk prostate cancer diagnosed within the last 12 months
2. Informed consent
3. Willing to take part in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 Years

Upper age limit
75 Years

Sex
Male

Total final enrolment
0

Key exclusion criteria
1. Those not fit for radical treatment
2. Those who have previously received treatment for prostate cancer (including radiotherapy, hormone therapy, brachytherapy or surgery)
3. Whose life expectancy is < 10 years
4. Either current or recent (≤12 months) treatment with finasteride or dutasteride
5. Currently enrolled or has been a participant within the last 30 days, in any other investigational drug or device study
6. Men not willing to comply with the procedural requirements of this protocol
7. Known allergy/sensitivity to, or intolerance of, finasteride or other 5-alpha reductase inhibitors, e.g., dutasteride. Known allergy to any excipients of finasteride
8. Any malignancy (other than non-melanoma skin cancer) that has not been in complete remission for five years
9. Any serious co-existent medical condition that would make repeat prostate biopsy hazardous
10. All contraindications to finasteride including concomitant therapy with any medication that may interact with finasteride
11. Any rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption
12. Men trying for a baby or with a pregnant partner

Date of first enrolment
15/08/2022

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Churchill Hospital Cancer Centre
Old Road
Oxford
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OX3 7LE

Study participating centre
Leeds Teaching Hospitals NHS Trust
Great George street
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Study participating centre
Bradford Teaching Hospital
Duckworth Lane
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BD9 6RJ

Study participating centre
Royal Hallamshire Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Glossop Road
Sheffield
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S10 2JF

Study participating centre
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Pinderfields Hospital
Aberford Road
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WF1 4DG

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Charity

Funder Name
Yorkshire Cancer Research

Alternative Name(s)
YCR

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 30/12/2021:
All data transferred between stakeholders will be covered by appropriate data sharing, data processing agreements or in the case of data transferred from trial sites to KCL, the site agreement. Trial data will be stored securely and made available for audit according to CPTU and KCTU SOPs. The Data Safe Haven for REDCap (AIMES https://www.aimes.uk/) will used to process and store data on behalf of Kings College London. The datasets generated and/or analysed during this study will be included in the subsequent results publication.

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Previous IPD sharing statement:
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Published as a supplement to the results publication, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		11/02/2025	13/02/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 7.0	27/03/2024	22/10/2024	No	Yes
Participant information sheet	version 8.0	11/12/2024	19/06/2025	No	Yes
Participant information sheet	Interview study, health professional version version 1.0	20/08/2025	17/11/2025	No	Yes
Participant information sheet	Interview study, patient version version 1.0	20/08/2025	17/11/2025	No	Yes
Participant information sheet	version 9.0	08/04/2026	09/07/2026	No	Yes
Protocol file	version 1.0	14/10/2021	07/02/2022	No	No
Protocol file	version 2.0	11/03/2022	04/04/2022	No	No
Protocol file	version 3.0	18/05/2022	06/07/2022	No	No
Protocol file	version 4.0	19/06/2023	02/10/2023	No	No
Protocol file	version 4.0	27/09/2023	12/12/2023	No	No
Protocol file	version 5.0	27/03/2024	22/10/2024	No	No
Protocol file	version 6.0	11/12/2024	19/06/2025	No	No
Protocol file	version 7.0	08/09/2025	17/11/2025	No	No
Protocol file	version 8.0	21/04/2026	09/07/2026	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes