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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 27/07/2021	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 27/08/2021	**Overall study status** Ongoing	
Last Edited 13/02/2025	**Condition category** Cancer	

Plain English Summary

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 commonest 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 choosing 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 550 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 December 2027

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

Study website
https://www.finessetrial.org/

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
2021-004004-17

IRAS number
1004290

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1004290, STH21032

Study information

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

Acronym
FINESSE

Study hypothesis

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

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Condition
Men with a new diagnosis of low- and intermediate-risk prostate cancer

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 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.

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

Overall study start date
16/04/2021

Overall study end date
31/12/2027

Eligibility

Participant inclusion criteria
Current participant inclusion criteria as of 12/12/2023:
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

Current 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

Age group
Mixed

Lower age limit
50 Years

Upper age limit
75 Years

Sex
Male

Target number of participants
550

Participant 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

Recruitment start date
15/08/2022

Recruitment end date
30/09/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Churchill Hospital Cancer Centre
Old Road
Oxford

United Kingdom
OX3 7LE

Study participating centre
Leeds Teaching Hospitals NHS Trust
Great George street
Leeds
United Kingdom
LS1 3EX

Study participating centre
Bradford Teaching Hospital
Duckworth Lane
Bradford
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Study participating centre
Royal Hallamshire Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Glossop Road
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United Kingdom
S10 2JF

Study participating centre
Mid Yorkshire Teaching NHS Trust
Pinderfields Hospital
Aberford Road
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Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.sheffield.ac.uk/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/03/2028

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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
HRA research summary			28/06/2023	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
Participant information sheet	version 7.0	27/03/2024	22/10/2024	No	Yes
Protocol file	version 5.0	27/03/2024	22/10/2024	No	No
Protocol article		11/02/2025	13/02/2025	Yes	No