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A study that aims to find out in the NHS what is the best way to take a prostate biopsy to determine if a man has prostate cancer (the TRANSLATE trial)

Submission date
19/01/2021

Recruitment status
No longer recruiting

Registration date
28/01/2021

Overall study status
Completed

Last Edited
31/12/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-the-best-way-to-take-tissue-samples-to-diagnose-prostate-cancer-the-translate (added 16/06/2012)

Background and study aims
Prostate cancer (PCa) is the second most common cancer in men in the United Kingdom (UK), with ~45,000 cases diagnosed per year. When a man has symptoms that may indicate they have PCa such as increased frequency of urination and consults their general practitioner (GP), the GP may perform a digital rectal examination (DRE) and a blood test to measure the level of a chemical termed Prostate-Specific Antigen (PSA). If either the DRE or PSA are abnormal then the GP may refer them to a hospital for investigation. 100,000 men each year in the UK are referred to hospitals for investigation.

At hospital the patients' symptoms, DRE and PSA are reviewed, and if appropriate the patient may be offered further tests for possible PCa, such as a pre-biopsy MRI scan and a prostate biopsy. The MRI scan allows detailed images of the prostate gland to be obtained, which may identify a possible PCa within the prostate gland. The patient may also be offered a prostate biopsy in order to obtain multiple small samples of the prostate tissue in order to identify possible PCa. A biopsy may be offered regardless of the MRI result (as not all PCa is visible on the MRI scan), but if an abnormal area is seen on the MRI scan then targeted biopsies can be taken from that specific region of the prostate gland. Regardless of the MRI scan result, regularly spaced 'systematic' biopsies of the prostate gland may be taken during the biopsy process, to maximise the chance of finding PCa on the biopsy if it is present.

The way in which specialists take biopsies for possible PCa varies across the country; however, no clear evidence exists as to which method is best – both in terms of detecting the PCa, and in terms of the occurrence of serious infection and other common side-effects of the biopsy process.
The methods most commonly used to obtain prostate biopsies for possible PCa are called:

1. A transrectal biopsy (known as a TRUS), where a needle is inserted into the prostate gland through an ultrasound imaging probe placed in the rectum (back passage). The ultrasound scan uses sound waves to give the doctors a view of the prostate gland whilst doing the biopsy, and a needle is used to take prostate tissue biopsy samples.
2. A transperineal biopsy (known as a TP), where the biopsy needle is passed directly through the skin (perineum) between the anus and the scrotum in order to take prostate tissue biopsy samples. An ultrasound probe is placed in the rectum in order to visualise the prostate gland, but instead of the needle passing up the ultrasound probe and through the wall of the rectum, it passes directly through the skin of the perineum.

TP biopsies have historically been performed under general anaesthetic (GA) where patients are put to sleep – however, this is an involved procedure requiring day case surgery, with the associated risks of a GA. A recent medical advance has been to perform the TP biopsy procedure under a local anaesthetic (LA), known as an LATP biopsy, where the skin of the perineum and deeper area around the prostate is numbed. In this study, the LATP biopsy is being directly compared against longstanding TRUS biopsy, in terms of detection of clinically significant PCa (i. e. cases of PCa that are likely to require treatment), and in terms of complications and costs of the procedure.

Who can participate?
Men under investigation for possible PCa (based on either an abnormal DRE or PSA) who have not have received a prostate biopsy previously

What does the study involve?
All men eligible for the study will have had a pre-biopsy MRI scan as part of the investigation for possible PCa. After obtaining informed consent they will be randomised (i.e. randomly allocated, as if 'by the toss of a coin') to either a TRUS biopsy or a LATP biopsy, with a 50% chance of being allocated to one or the other type of biopsy. Following the biopsy procedure, the men will be followed up by the study in order to determine the rate of detection of clinically significant PCa rate in each biopsy group. The researchers will also check for the occurrence of any post-biopsy infections, and other patient-reported biopsy-related complications such as bleeding, bruising, pain, and loss of erections and sexual function. Additionally, the researchers will record any subsequent prostate biopsy procedures, which might be recommended if the first prostate biopsy has produced a possible 'false negative' result, where clinicians have concerns that the prostate biopsy result is inconsistent with the pre-biopsy MRI scan result. Data will be collected before the biopsy (baseline), immediately after the biopsy, and then at 7 days, 35 days and 4 months following the biopsy.

What are the possible benefits and risks of participating?
The risks of each procedure are unchanged whether an individual receives them as part of the trial or outside of the trial. The trial aims to provide a definitive answer for men presenting to hospitals with suspected prostate cancer which biopsy method is ultimately the best for men.

Where is the study run from?
Oxford Clinical Trials Research Unit (OCTRU) Surgical Intervention Trials Unit (UK)

When is the study starting and how long is it expected to run for?
From January 2021 to March 2024

Who is funding the study?
National Institute for Health Research - Health Technology Assessment (NIHR HTA) (UK)

Who is the main contact?
TRANSLATE Trial Manager
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
293939

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HTA - NIHR131233

Study information

Scientific Title
A randomised controlled trial of TRANSrectal biopsy versus Local Anaesthetic Transperineal biopsy Evaluation (TRANSLATE) of potentially clinically significant prostate cancer (the TRANSLATE trial)

Acronym
TRANSLATE

Study objectives

The overall aim is to assess whether LATP biopsy improves detection of clinically significant PCa compared to TRUS biopsy, while remaining tolerable to men and reducing rates of infection in a UK-based multicentre RCT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at the time of registration

Study design
Multicentre two-arm interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

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

Interventions
1042 biopsy-naïve men referred with suspected PCa on the basis of an elevated age-specific prostate-specific antigen (PSA) or abnormal digital rectal examination (DRE), and suitable for investigation with a pre-biopsy MRI and prostate biopsy, are randomised 1:1 to either intervention or comparator.

Intervention: LATP (local anaesthetic transperineal) prostate biopsy. This will be performed with an average of 12 biopsy cores in 6 sectors depending on prostate size, plus typically 4 target cores per MRI lesion, using the “Precision-Point” access system, and the BK UA1232 device, both of which are used in a virtually identical fashion. Preliminary cohorts using both devices reveal that detection, infection and tolerability rates are almost identical.

Comparator: TRUS (transrectal ultrasound-guided) prostate biopsy. This will be performed according to each hospital’s standard practice, with an average of 12 biopsy cores, in two sectors with additional target pots (typically 4 target cores per MRI lesion). The number of biopsies taken will be equivalent, regardless of whether acquired by an LATP or TRUS biopsy approach.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Clinically significant prostate cancer (PCa), defined as Gleason Grade Group ≥2, detected using LATP/TRUS biopsy within 5 days of the samples being taken

Key secondary outcome(s))
1. Rates of infection measured using patient-reported questionnaires at 7 and 35 days, and 4 months
2. Health-related quality of life measured using the validated questionnaires International Index for Erectile Function (IIEF), International Prostate Symptom Score (I-PSS), Expanded Prostate

Cancer Index Composite (EPIC), bowel assessment, and EuroQol Group quality of life questionnaire (EQ-5D-5L) at 7 and 35 days, and 4 months
3. Patient-reported tolerability of the procedure measured using the Patient Reported Outcomes Burdens and Experiences (ProBE) questionnaire (perception part only) immediately after the procedure
4. Patient-reported biopsy-related complications (including bleeding, bruising, pain, and loss of erectile function) measured using the ProBE questionnaire at 1 week
5. Number of subsequent prostate biopsy procedures required measured using a patient diary that is collected and reviewed at 4 months
6. Cost-effectiveness measured using a trial specific resource questionnaire at baseline, 7, and 35 days, and 4 months
7. Histological parameters (ISUP grade group, cancer core length, core involvement ,and target biopsy cancer parameters) measured using standard NHS histology reporting of biopsy samples within 5 days of the samples being taken
8. Burden and rate of detection of clinically insignificant (Gleason Grade Group 1) PCa measured using standard NHS histology reporting of biopsy samples within 5 days of the samples being taken

Completion date
28/03/2024

Eligibility

Key inclusion criteria
All biopsy-naïve men who (regardless of age), during an investigation for suspicion of possible PCa, require a prostate biopsy and who have had one or more of the below findings:
1. A PSA value above the age-adjusted upper limit of normal, regardless of the MRI result
2. An abnormal pre-biopsy MRI
3. An abnormal prostate DRE (regardless of serum PSA or MRI result)
4. Considered suitable to tolerate a LATP biopsy procedure

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
1126

Key exclusion criteria
1. Had a previous prostate biopsy
2. Dysuria on the day of biopsy or untreated urinary tract infection (UTI)
3. Immunocompromised (due to history of prior immunocompromising medical condition, or

medications e.g. steroids or methotrexate)
4. May need enhanced antibiotic prophylaxis (e.g. due to indwelling catheter or recurrent UTIs)
5. Previous abdominoperineal resection (i.e. absent rectum)
6. Unable to recline adequately in Lloyd-Davis / lithotomy position (e.g. hip surgery or contractures)
7. Unable to have a pre-biopsy MRI (e.g. pacemaker, eGFR <50, or claustrophobia)
8. PSA >50 ng/ml (i.e. locally advanced/metastatic PCa easily detectable by TRUS)

Date of first enrolment
03/12/2021

Date of final enrolment
26/09/2023

Locations

Countries of recruitment
United Kingdom

Study participating centre
Oxford University Hospitals NHS Foundation Trust
Churchill Hospital
Oxford
England
OX3

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/12/2025	17/12/2025	Yes	No
Statistical Analysis Plan		14/06/2024	19/06/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes