

Magnetic resonance imaging-targeted biopsy compared to standard trans-rectal ultrasound guided biopsy for the diagnosis of prostate cancer in men without prior biopsy

Submission date 29/04/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 29/04/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/08/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-using-mri-to-help-diagnose-prostate-cancer-precision>

Contact information

Type(s)

Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT02380027

Protocol serial number

18902

Study information

Scientific Title

PRostate Evaluation for Clinically Important disease: Sampling using Image-guidance Or Not?

Acronym

PRECISION

Study objectives

1. The proportion of men with clinically significant cancer detected by multi-parametric MRI-targeted biopsy (MRI-TB) will be no less than that detected by standard 12-core TRUS biopsy
2. The proportion of men with clinically insignificant cancer detected by multi-parametric MRI-targeted biopsy (MRI-TB) will be less than that detected by standard 12-core TRUS biopsy

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Research Ethics Service Committee East Midlands - Leicester, ref: 15/EM/0188

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Diagnosis

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Cancer, Renal disorders; Subtopic: Prostate Cancer, Renal disorders; Disease: Prostate, All Renal disorders

Interventions

Arm 1 - 12-core transrectal prostate biopsy

Men undergo standard 12-core transrectal prostate biopsy. A trans-rectal ultrasound probe is used to visualise prostate anatomy and 12 prostate samples are taken. This may be done under local anaesthetic.

Arm 2 - MRI arm.

Men undergo a multi-parametric MRI. If there is a suspicious area then these men undergo MRI-targeted prostate biopsy. Up to three suspicious areas are targeted with up to 4 cores to each suspicious area. Software assisted registration may be used. A trans-rectal ultrasound probe is used to visualise prostate anatomy and the prostate samples are taken. This may be done under local anaesthetic. Men with an MRI without any suspicious areas do not undergo biopsy.

Men in each arm are followed up routinely for 30-days post intervention.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Proportion of men with clinically significant cancer detected

Key secondary outcome(s)

1. Proportion of men with clinically insignificant cancer detected
2. Proportion of men in MPMRI arm who avoid biopsy
3. Proportion of men in whom MPMRI score for suspicion of clinically significant cancer was 3, 4 or 5 but no clinically significant cancer was detected
4. Proportion of men who go on to definitive local treatment (e.g. radical prostatectomy, radiotherapy, brachytherapy) or systemic treatment (e.g. hormone therapy, chemotherapy)
5. Cancer core length of the most involved biopsy core (maximum cancer core length, MCCL)
6. Proportion of men with post-biopsy adverse events
7. Health related quality of life
8. Proportion Gleason grade upgrading in men undergoing radical prostatectomy
9. Cost per diagnosis of cancer

Completion date

01/12/2017

Eligibility**Key inclusion criteria**

1. Men at least 18 years of age referred with clinical suspicion of prostate cancer who have been advised to have a prostate biopsy
2. Serum PSA \leq 20ng/ml
3. Suspected stage \leq T2 on rectal examination (organ-confined prostate cancer)
4. Fit to undergo all procedures listed in protocol
5. Able to provide written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Male

Total final enrolment

500

Key exclusion criteria

1. Prior prostate biopsy
2. Prior treatment for prostate cancer

3. Contraindication to MRI
4. Contraindication to prostate biopsy
5. Men in whom artifact would reduce the quality of the MRI
6. Previous hip replacement surgery, metallic hip replacement or extensive pelvic orthopaedic metal work
7. Unfit to undergo any procedures listed in protocol

Date of first enrolment

01/07/2015

Date of final enrolment

01/10/2017

Locations

Countries of recruitment

United Kingdom

England

Belgium

Canada

Finland

France

Italy

Netherlands

Study participating centre

Erasmus University Medical Centre

Netherlands

-

Study participating centre

Helsinki University Hospital

Finland

-

Study participating centre

Ghent University Hospital
Belgium

-

Study participating centre
Jewish General Hospital
Canada

-

Study participating centre
North West London Hospitals NHS Trust
United Kingdom
HA1 3UJ

Study participating centre
Radboud University
Nijmegen Medical Centre
Netherlands

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Study participating centre
Royal Free London NHS Foundation Trust
United Kingdom
NW3 2QG

Study participating centre
Sapienza University of Rome
Italy

-

Study participating centre
University Lille Nord de France
France

-

Study participating centre

University College London Hospital (lead site)
United Kingdom
NW1 2BU

Sponsor information

Organisation

UCL Clinical Trials Unit

ROR

<https://ror.org/001mm6w73>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/05/2018	09/08/2019	Yes	No
Protocol article	protocol	12/10/2017	09/08/2019	Yes	No
HRA research summary			28/06/2023	No	No