ISRCTN18440098 https://doi.org/10.1186/ISRCTN18440098

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

Registration date
29/04/2015

Overall study status
Completed

Last Edited
09/08/2019

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02380027

Secondary identifying numbers
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

Study design
Randomised; Interventional; Design type: Diagnosis

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 participant information sheet

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 measure
Proportion of men with clinically significant cancer detected

Secondary outcome measures
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

Overall study start date
01/07/2015

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 ≤ 20ng/ml
3. Suspected stage ≤ 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

Age group

Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
Planned Sample Size: 470; UK Sample Size: 150

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
Belgium

Canada

England

Finland

France

Italy

Netherlands

United Kingdom

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
-

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

Sponsor details
Rockefeller Office Room 233
Rockefeller Building
21 University Street
London
England
United Kingdom
WC13 6DE

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	12/10/2017	09/08/2019	Yes	No
Results article	results	10/05/2018	09/08/2019	Yes	No
HRA research summary			28/06/2023	No	No