

Prostate MRI imaging study

Submission date 07/12/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/12/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/03/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-more-detailed-type-mri-scan-help-improve-diagnosis-prostate-cancer-promis>

Study website

<http://www.ctu.mrc.ac.uk/promis.aspx>

Contact information

Type(s)

Scientific

Contact name

Prof Mark Emberton

Contact details

MRC Clinical Trials Unit at UCL
Institute of Clinical Trials and Methodology
Aviation House
125 Kingsway
London
United Kingdom
WC2B 6NH
-
MRCCTU.PROMIS@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01292291

Secondary identifying numbers

PROMIS PR11; HTA 09/22/67

Study information

Scientific Title

PROstate MRI Imaging Study (PROMIS): evaluation of multi-parametric magnetic imaging in the diagnosis and characterisation of prostate cancer

Acronym

PROMIS

Study objectives

1. In men identified with clinical suspicion of prostate cancer, those with favourable MP-MRI results could safely avoid unnecessary biopsy
2. An MP-MRI based pathway can improve the rate of detection of clinically significant cancer as compared to TRUS biopsy
3. An MP-MRI based diagnostic pathway can be cost-effective

More details can be found at: <https://www.journalslibrary.nihr.ac.uk/programmes/hta/092267/#/>

Ethics approval required

Old ethics approval format

Ethics approval(s)

North West London Research Ethics Committee, 16/03/2011, ref: 11/LO/0185

Study design

Prospective validating paired cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

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

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

All patients will receive the same treatment - Multi-parametric MRI scan and the combined prostate biopsy procedure (Template Prostate Mapping biopsy [TPM], followed by Trans Rectal Ultrasound Biopsy [TRUS]).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Proportion of men who could safely avoid biopsy as determined by specificity and negative predictive values
2. Proportion of men correctly identified by MP-MRI to have clinically significant prostate cancer as determined by sensitivity and positive predictive values [an overall MP-MRI score will be given from 1-5 (definite benign 1, probably benign 2, indeterminate 3, probably malignant 4, definitely malignant 5), where the primary definition of a positive result is MP-MRI score of ≥ 3]
3. Primary definition of cancer according to biopsy: Dominant Gleason pattern ≥ 4 and/or cancer core length ≥ 6 mm

Secondary outcome measures

1. Evaluation of MRI according to secondary definition of prostate cancer (Dominant Gleason pattern ≥ 4 and/or cancer core length ≥ 4 mm)
2. Evaluation of the optimal combination of MP-MRI parameters (T2, DW, DCE)
3. Cost-effectiveness
4. Inter-observer variation in the reporting of MP-MRI
5. Evaluation of factors associated with detection of clinically significant prostate cancer
6. Outcomes associated with translational work

Overall study start date

28/03/2012

Completion date

28/04/2015

Eligibility

Key inclusion criteria

1. Are aged 18 years or over, are at risk of prostate cancer and have been advised to have a prostate biopsy
2. Have a serum prostate-specific antigen (PSA) value of less than or equal 15ng/ml in the last 3 months
3. Have suspected less than or equal T2 on rectal examination
4. Are fit for general/spinal anaesthesia and all study procedures

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

714

Key exclusion criteria

Current exclusion criteria as of 22/05/2012:

1. Have been treated using 5-alpha reductase inhibitors at time of registration or during the prior 6 months
2. Have a previous history of prostate biopsy, prostate surgery or treatment for prostate cancer
3. Have urinary tract infection or history of acute prostatitis within the last 3 months
4. Have a contraindication to MRI or any other medical condition precluding study procedures
5. Previous history of hip replacement surgery, metallic hip replacement or extensive pelvic orthopaedic metal work.

Previous exclusion criteria:

1. Have been treated using 5-alpha reductase inhibitors at time of registration or during the prior 6 months
2. Have a previous history of prostate biopsy, prostate surgery or treatment for prostate cancer
3. Have urinary tract infection or history of acute prostatitis within the last 3 months
4. Have a contraindication to MRI or any other medical condition precluding study procedures
5. Have previous history of hip replacement surgery

Date of first enrolment

28/03/2012

Date of final enrolment

28/04/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

MRC Clinical Trials Unit at UCL

London

United Kingdom

WC2B 6NH

Sponsor information

Organisation

University College London (UK)

Sponsor details

c/o Professor Mark Emberton
Division of Surgery and Interventional Sciences
67 Riding House Street
London
England
United Kingdom
W1P 7NN
-
m.emberton@ucl.ac.uk

Sponsor type

University/education

Website

<http://www.ucl.ac.uk/>

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

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

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/05/2015		Yes	No
Results article	results	25/02/2017		Yes	No
Results article	results	01/07/2018		Yes	No
Plain English results			24/03/2022	No	Yes