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Prostate MRI imaging study

Submission date 07/12/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/12/2011	**Overall study status** Completed	
Last Edited 24/03/2022	**Condition category** Cancer	

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

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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
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Sponsor information

Organisation
University College London (UK)

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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