

# Prostate MRI imaging study

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

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT01292291

### Protocol serial number

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

**Study type(s)**

Diagnostic

**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(s)**

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  $\geq 3$ ]  
3. Primary definition of cancer according to biopsy: Dominant Gleason pattern  $\geq 4$  and/or cancer core length  $\geq 6$  mm

### **Key secondary outcome(s)**

1. Evaluation of MRI according to secondary definition of prostate cancer (Dominant Gleason pattern  $\geq 4$  and/or cancer core length  $\geq 4$  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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

Male

### **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**

United Kingdom

England

**Study participating centre**

**MRC Clinical Trials Unit at UCL**

London

United Kingdom

WC2B 6NH

## Sponsor information

**Organisation**

University College London (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, 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**

Not provided at time of registration

**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	25/02/2017		Yes	No
<a href="#">Results article</a>	results	01/07/2018		Yes	No
<a href="#">Protocol article</a>	protocol	01/05/2015		Yes	No
<a href="#">Plain English results</a>			24/03/2022	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes