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A comparison of the accuracy of ultrasound scanning and MRI in the detection significant prostate cancer.

Submission date 09/03/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/06/2016	**Overall study status** Completed	
Last Edited 24/11/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-using-ultrasound-scans-to-diagnose-prostate-cancer-camdus

Contact information

Type(s)
Public

Contact name
Mr Alistair Grey

Contact details
Room 4.23
132 Hampstead Rd
London
United Kingdom
NW1 2PS
+44 (0)20 7679 9092
alistair.grey@ucl.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT02712684

Protocol serial number
UCL reference 15/0473

Study information

Scientific Title
Multi-parametric ultrasound targeted biopsies compared to multi-parametric MRI targeted biopsies in the diagnosis of clinically significant prostate cancer

Study objectives
Multiparametric ultrasound has a comparable performance to multiparametric MRI in the detection and risk stratification of prostate lesions that warrant biopsy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London (Brent East), 08/10/2015, ref: 15/LO/1331

Primary study design
Observational

Study design
Prospective multi-centre cohort diagnostic utility study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
Men who require a prostate biopsy will be approached and consented to enter this study. Participants will all undergo pre-biopsy mp-MRI (reference test) and mp-USS (index test) of the prostate. Only men with positive scans will undergo prostate biopsy. The order in which lesions discovered on mp-MRI or on mp-USS are sampled will be randomised. All biopsies will be taken via the transperineal route in a single procedure. Comparison will be drawn between biopsy results of lesions detected by mp-USS with those lesions detected by mp-MRI. Consideration will be given as to whether a lesion detected by one imaging modality is the same abnormality as one detected by the other imaging modality, in the same patient. Analysis will be carried out at both the level of the lesion and the whole prostate. Men without suspicious lesions on either imaging modality will not proceed to biopsy. The first 20 patients recruited will comprise an internal pilot to ensure we are carrying out high quality mp-USS studies.

Intervention Type
Device

Primary outcome(s)
The proportion of men with a lesion detected using each diagnostic strategy and the proportion of men subsequently diagnosed with clinically significant prostate cancer as defined histologically as UCL/Ahmed definition 1 (Gleason 4+3 or greater and/or maximum cancer core length of 6mm or greater).

Key secondary outcome(s)
1. The proportion of men diagnosed with clinically significant prostate cancer by each diagnostic strategy as defined histologically using other thresholds for clinical significance, namely:
1.1. UCL/Ahmed definition 2: Gleason >3+4 and/or Maximum cancer core length >4mm
1,2. Gleason >3+4 and/or MCCL >6mm
1.3. Any length of Gleason >3+4
1.4. Any length of Gleason >4+3
2. The proportion of men diagnosed with clinically significant cancer (using all of the pre-specified definitions based on histology) by using the combination of these two imaging techniques versus either modality alone.
3. The proportion of men diagnosed with clinically significant prostate cancer (using all of the pre-specified definitions based on histology) when:
3.1. mp-USS targeted biopsies are carried out first compared to being carried out second and when order in which the targeted biopsies are carried out
3.2. mp-MRI targeted biopsies are carried out first compared to being carried out second
4. The proportion of men from the cohort who progress to radical prostatectomy, and have whole mount histology that matches the results of the mp-USS, mp-MRI and targeted biopsy.
5. Proportions of adverse events, log of resource utilization and health-related quality-of-life measures on the EQ-5D-5L questionnaire
6. A cohort of men, consented for long-term follow-up and linkage, providing the potential for further translational and clinical studies

Completion date
30/04/2019

Eligibility

Key inclusion criteria
1. A potential need for prostate biopsy indicated by raised PSA or other clinical parameter, the final decision over which will be taken after imaging.
2. PSA </=20ng/ml measured within 6 months of screening visit
3. An understanding of the English language sufficient to understand written and verbal information about the trial and consent process
4. Estimated life expectancy of 5 years or more
5. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
370

Key exclusion criteria
1. Any contraindication to the ultrasound contrast agent including right to left shunt, pulmonary hypertension and uncontrolled hypertension. Also patients with an acute coronary syndrome within the last 6 months or ischaemic heart disease that's not well controlled by medication.
2. Any form of androgen deprivation or hormones (except 5-alpha reductase inhibitors) within 6 months of screening visit
3. Irreversible coagulopathy predisposing to bleeding
4. Inability to undergo transrectal ultrasonography
5. Prostate volume, measured at the time of mp-USS if previously unknown, of >60cc.
6. Previous radiation therapy to the prostate
7. Previous HIFU, cryosurgery, thermal therapy, irreversible electroporation, photodynamic, photothermal therapy, microwave or injectable toxin therapy to the prostate.
8. Transurethral resection or vaporization of the prostate for benign prostatic hyperplasia using any energy modality within 6 months of screening visit
9. Nodal or metastatic prostate cancer on any form of imaging at any time-point
10. Not fit for general anaesthetic
11. Unable to give informed consent
12. Any other condition the investigator considers would make the patient unsuitable

Date of first enrolment
01/03/2016

Date of final enrolment
01/01/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College Hospital London
235, Euston Rd
Fitzrovia
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
UCL Comprehensive Clinical Trials unit

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Prostate Cancer UK

Alternative Name(s)
Prostate Cancer, Prostate Action, ProstateUK, prostatecanceruk

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Moulton Foundation

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2022	04/03/2022	Yes	No
Protocol article	protocol	01/03/2018	30/11/2020	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results			24/11/2022	No	Yes