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Can new ultrasound scanning methods improve detection of prostate cancer?

Submission date
29/04/2019

Recruitment status
No longer recruiting

Registration date
08/05/2019

Overall study status
Completed

Last Edited
01/12/2022

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-high-resolution-ultrasound-to-diagnose-prostate-cancer

Background and study aims
Prostate cancer is the fourth most common cause of death from cancer in Scotland and the second most common for men. Its incidence in the UK has risen 44% since the early 1990s and is still on the rise. With 11,000 deaths per year in the UK, prostate cancer causes more deaths than breast cancer. However, compared to breast cancer, the screening and diagnosis of prostate disease has not improved significantly over the years. Men with higher prostate specific antigen (PSA) levels in their blood undergo biopsy (taking a small piece of prostate tissue and looking for cancer cells), which is not very accurate as cancer is sometimes missed. This is because biopsy procedures only take small sections of the prostate, but also because PSA is not a good marker of prostate cancer, because not all men with high PSA levels have prostate cancer and some men with prostate cancer have normal levels of PSA.
Ultrasound imaging is a common way to produce medical images of organs within the body. It uses sound waves at a very high frequency, higher than humans can hear. The sound is transmitted into the body and the echoes are detected and used to create an image. To get better images, contrast agents can be used. These are tiny bubbles (about the same size as a red blood cell) that are injected into the patient. They give very big echoes and so can make the image clearer in places where the contrast agent is located. The contrast agent stays in the blood stream so will only go where the blood goes. This makes it very good for trying to get pictures of blood vessels.
Tumours are areas which have a lot of very small blood vessels. Ultrasound imaging cannot clearly separate the tiny vessels that make up tumours because they are too small. We want to try super-resolution imaging (SRI) using contrast enhanced ultrasound (CEUS). To do this, we will save videos which are 2-3 minutes long, of the tiny bubbles flowing through the prostate and later, we will run computer programmes which will detect the echoes from the bubbles and track them through the prostate, hopefully making a image that shows the path the bubbles take through the blood vessels and showing us where the tumour in the prostate is located.
In this study, we aim to find out whether SRI can detect prostate cancer accurately. This will help identify the potential of the method for detecting the disease at an early stage and may replace unnecessary biopsies.

Who can participate?
Men already diagnosed with prostate cancer who have decided to have their prostate removed surgically as their main treatment.

What does the study involve?
In the operating theatre, when the patient is already under anaesthetic and just before the prostate is removed, we will perform ultrasound scans of the prostate. The patient will be injected with an ultrasound contrast agent and we will scan the prostate gland with a probe placed into the rectum (back passage). All participants will have this done. We will then compare the findings of the ultrasound scan to the true features of the prostate tumour that are seen once it is examined after removal.

What are the possible benefits and risks of participating?
There is no direct benefit to the participants. They will assist in a study that could lead to improved accuracy in prostate cancer diagnosis. There is a theoretical risk of allergic reaction to the contrast agent injection but this risk is extremely small.

Where is the study run from?
Heriot-Watt University (UK) and NHS Lothian Western General Hospital (UK).

When is the study starting and how long is it expected to run for?
November 2017 to April 2024

Who is funding the study?
Chief Scientist Office in Scotland (UK)

Who is the main contact?
Dr Vassilis Sboros, V.Sboros@hw.ac.uk

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
TCS/18/40

Study information

Scientific Title
Development of a new image processing method for super-resolution contrast-enhanced ultrasound (SR-CEUS) imaging of prostate tumours

Acronym
Super-resolution ultrasound imaging for prostate cancer

Study objectives
Super-resolution contrast-enhanced ultrasound (SR-CEUS) imaging can accurately diagnose prostate tumours.

Ethics approval required
Old ethics approval format

Ethics approval(s)
To be submitted to South East Scotland Research Ethics Committee Node following trial registration.

Study design
Single-centre observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

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

Interventions
This is a single cohort non-comparative diagnostic study. The intervention is super-resolution contrast enhanced ultrasound imaging of the prostate with a new image processing method. Patients with prostate cancer who have elected to have prostatectomy will be asked to consider participation in the trial at a routine clinic visit. In the operating theatre, when the patient is already under anaesthetic for their planned prostate removal, we will perform ultrasound scans of the prostate. Whilst under anaesthetic, the patient will be injected with an ultrasound contrast agent and we will scan the prostate gland with a probe placed in to the rectum. All participants will have this done. The scheduled prostate removal will then be performed as usual. At a later date after processing the ultrasound video data we will compare the findings of the ultrasound scan to the true features of the prostate tumour that are seen once the specimen is examined after removal. The ultrasound scans should take 20-30 minutes per patient. There will be no follow-up for the patient after the ultrasound scans and no other contact or input is required from the patient for the purposes of the study. Normal clinical follow-up will apply.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Identification of index prostate tumours by SR-CEUS. The data will be collected during the ultrasound scan, with approximately 30 mins in total for multiple videos to be saved. Histological prostate gland examination will be performed by a pathologist within 2 weeks of ultrasound scan and used as the reference standard.

Key secondary outcome(s))
1. The comparative accuracy of bolus and continuous infusion of contrast regimes for prostate tumour detection
2. A qualitative assessment of the benefits of each contrast agent to include:
2.1. Feasibility of full image acquisition within maximum allowed dosage
2.2. Resolution of tumour imaging
2.3. Qualitative assessment of preference from the radiologist performing the procedure
3. Duration of ultrasound scanning required to obtain a full image set of the prostate gland
4. The association of prostate tumour SR-CEUS microvascular structure with prostate tumour pathological Gleason grade and pathological t stage
5. Tumour volume measured by SR-CEUS and using pathology techniques
6. Tumour volume location measured by SR-CEUS and using pathology techniques

For all outcomes, the ultrasound videos will be saved after the procedure and processed using Matlab and ImageJ software at a later date, usually within the weeks after the original ultrasound scan. The resulting images from the ultrasound analysis will be compared to each other and to histological prostate data. The location and size of the tumour regions in the histology will be compared to that detected in the processed ultrasound data.

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. Known or suspected prostate cancer
2. Already planned to undergo radical prostatectomy as the primary treatment modality

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
1. Unable or unwilling to give consent
2. Known allergy to the ultrasound contrast agent

Date of first enrolment
01/09/2019

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Lothian Western General Hospital
Crewe Road South
Edinburgh
United Kingdom
EH4 2XU

Sponsor information

Organisation
Heriot-Watt University

ROR
https://ror.org/04mghma93

Organisation
NHS Lothian

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes