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# Which biopsy method to choose when men have abnormal PSA and/or DRE, a randomized study comparing current practice with innovative practice

**Submission date**
26/12/2016

**Recruitment status**
No longer recruiting

**Registration date**
28/12/2016

**Overall study status**
Completed

**Last Edited**
11/08/2022

**Condition category**
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Prostate cancer is one of the most common forms of cancer in men. Symptoms often develop slowly, over a long period of time and often involve an increased need to urinate, straining while urinating, and feeling unable to fully empty the bladder, because the enlarged prostate is pushing against the urethra (the tube that carries urine from the bladder to the penis). Diagnosing prostate cancer usually starts with measuring levels of a protein called PSA which is produced by the prostate and is higher than normal when the prostate is enlarged. Prostate cancer is often confirmed using a technique called transrectal ultrasound-guided biopsy (TRUS; a procedure where samples (cores) are taken to test in the laboratory for cancer cells). Although widely used, TRUS can sometimes miss cancerous growths and so a more accurate means of diagnosis is needed. Ultrasound CT with artificial intelligence (AI-US-CT) is a scanning technique that can potentially improve the accuracy of TRUS. The aim of this study is to find out whether AI-US-CT can improve the accuracy of TRUS with less cores being taken.

Who can participate?
Men with higher than normal PSA levels.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group have six samples (core biopsies) taken guided by AI-US-CT, while the patient is lying down. Those in the second group receive a traditional TRUS biopsy, where 12 samples are taken. Those in the third group also have 12 samples taken but the process is guided using a different type of scan (MRI). Participants in all groups have their results reviewed one week after the samples are taken to assess prostate cancer detection rates.

What are the possible benefits and risks of participating?
Patients could benefit from new practice of prostate biopsy with less cores (samples taken) and higher detection rate. There are no notable risks other than the general risks of complications from biopsy, such as bleeding and infection.

Where is the study run from?
1. The First Affiliated Hospital, College of Medicine, Zhejiang University (China)
2. Zhejiang University International Hospital (China)
3. Wu Jieping Urology Center (China)
4. Peking university Shougang Hospital (China)

When is the study starting and how long is it expected to run for?
January 2015 to December 2017

Who is funding the study?
Zhejiang Province Key Project of Science and Technology (China)

Who is the main contact?
1. Dr Xiao Wang (public)
2. Professor Liping Xie (scientific)

# Contact information

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Scientific

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
AI-US-CT2016

## Study information

### Scientific Title
A randomized controlled trial to assess and compare the outcomes of AI-US-CT-guided biopsy, transrectal ultrasound-guided 12-core systematic biopsy, and mpMRI-assisted 12-core systematic biopsy

### Study objectives
The AI-US-CT targeted 6-core biopsy illustrates a higher detection rate of prostate cancer with less cores in comparison to transrectal ultrasound guided 12-core systematic biopsy and mpMRI assisted 12-core systematic biopsy.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics Committee of the First Affiliated Hospital, College of Medicine, Zhejiang University, 22/02/2016, ref: 201644

### Study design
Multi-centre randomized controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Diagnostic

### Participant information sheet
No participant information sheet available

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

### Interventions
Patients are randomly assigned in a 1:1:1 ratio to one of three groups using a computer-generated list of random numbers. Patients are allocated by an independent third party to ensure that the randomization group could not be predicted.

AI-US-CT group: All transrectal ultrasound scans are performed with the patients lying in a left lateral position. Transaxial images are generated at 5 mm intervals beginning at the prostate apex and proceeding cephalad until the seminal vesicles were reached. Images are sent to AI-US-CT online-center for analysis. Six-core targeted biopsies were performed by one urologist from the third party with experience of more than 50 AI-US-CT targeted biopsy at the start of the study.

Systematic biopsy group: Patients receive traditional transrectal ultrasound guided 12-core systematic biopsy by one urologist from the third party with more than 10 years prostate biopsy experience at the start of the study.

mpMRI group: Patients undergo pre-biopsy mp-MRI of the prostate and receive mpMRI assisted 12-core systematic biopsy by one urologist from the third party with ore than 10 years prostate biopsy experience at the start of the study.

All patients receive routine anti-infective therapy. If the patient is diagnosed of prostate cancer by pathologists, he will subsequently receive operation or/and androgen deprivation therapy or /and castration therapy or/and radiotherapy according to clinical stage of the disease, otherwise PSA will be re-examined every 6 months.

### Intervention Type
Procedure/Surgery

### Primary outcome measure
Prostate cancer detection rate is assessed through medical record review 1 week post-test.

### Secondary outcome measures
1. The positive rate for biopsy cores is assessed through medical record review 1 week post-test
2. The number of biopsy cores needed to detect one prostate cancer is acquired through medical record review 1 week post-test
3. In mpMRI group, the prostate cancer detection rate for each PI-RADS category is acquired through medical record review 1 week post-test

### Overall study start date
01/01/2015

### Completion date
31/12/2017

## Eligibility

### Key inclusion criteria

1. Male
2. Under 85 years of age
3. Verified prostate-specific antigen (PSA) > 4 ng/ml and/or abnormal DRE
4. Provision of signed informed consent

### Participant type(s)
Patient

### Age group
Adult

### Sex
Male

### Target number of participants
120 for each group

### Total final enrolment
450

### Key exclusion criteria
1. No signed informed consent
2. Patients who have been included in published cohorts

### Date of first enrolment
22/02/2016

### Date of final enrolment
31/03/2017

## Locations

### Countries of recruitment
China

### Study participating centre
**The First Affiliated Hospital, College of Medicine, Zhejiang University**
79 Qingchun Road
Hangzhou
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### Study participating centre
**Zhejiang University International Hospital**
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**Study participating centre**
**Wu Jieping Urology Center**
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**Study participating centre**
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9 Jinyuanzhuang Road
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# Sponsor information

**Organisation**
Science Technology Department of Zhejiang Province

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33 Huan Cheng Xi Road
Hangzhou
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**Sponsor type**
Government

**ROR**
https://ror.org/05yj3y977

# Funder(s)

**Funder type**
Government

**Funder Name**

Zhejiang Province Key Project of Science and Technology

# Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal and set the intent to publish date around one year after our overall trial end date.

### Intention to publish date
31/12/2018

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Xiao Wang (zjuwangxiao@126.com)

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 19/07/2022 | 11/08/2022 | Yes | No |