

Prostate health index density in the diagnosis of clinically significant prostate cancer in equivocal magnetic resonance imaging of the prostate in the Taiwan community

Submission date 29/02/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/03/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/07/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

This study investigates the efficacy of prostate health index density (PHID) for the guidance of MRI-directed prostate biopsies in accurately identifying clinically significant prostate cancers (csPCa), with a focus on populations within Taiwan.

Who can participate?

Men with Prostate Health Index (PHI) and MRI-guided targeted and/or systematic prostate biopsy performed were included.

What does the study involve?

This study involves collecting information from multiple medical centers in Taiwan about prostate biopsies. We're looking at various factors like PSA levels, prostate size, Prostate Health Index, and how these relate to MRI PI-RADS scores using different analytical methods. Our goal is to identify clinically significant prostate cancer (csPCa), which is cancer that has a meaningful impact on health, particularly focusing on minimizing unnecessary biopsies.

What are the possible benefits and risks of participating?

None

Where is the study run from?

Taipei Veterans General Hospital (Taiwan)

When is the study starting and how long is it expected to run for?

April 2016 to Dec 2022

Who is funding the study?

Investigator initiated and funded

Who is the main contact?
Dr Ching-Hsin Chang, josp1029@gmail.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr Ching-hsin Chang

ORCID ID

<https://orcid.org/0000-0003-4055-8853>

Contact details

No. 252, Wuxing St, Xinyi District
Taipei City
Taiwan
110
+886-2-2737-2181
123001@h.tmu.edu.tw

Additional identifiers

Protocol serial number

VGHTPE No. 2017-08-017A

Study information

Scientific Title

Prostate Health Index Density in the diagnosis of Clinically significant prostate cancer in PI-RADS 3 of prostate mpMRI in the Taiwan community

Study objectives

We put more interest in the proper PHID cut-off value among mpMRI PI-RADS 3 patients. Eventually, we want to establish a flowchart for Taiwanese, including PSA, PHID, and mpMRI.

Ethics approval required

Ethics approval not required

Ethics approval(s)

This protocol was based on the current clinical practice

Study design

Observational cohort

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Prostate cancer screening

Interventions

This is a multicenter study of Taiwan men with PHI and MRI-targeted and systematic prostate biopsies performed. From 2016 to 2022, after obtaining informed consent, we enrolled patients who were more than 40 years and underwent MRI-targeted prostate biopsy for suspicious PCa due to elevated serum PSA level (PSA > 4 ng/mL)

Prostate biopsy derived from both MRI-targeted and systematic biopsies. The database included data from 3 medical centers in Taiwan. The algorithm was modified from pilot studies. Patients included in the database had blood samples collected prior to MRI-targeted and systematic prostate biopsies. The collected blood samples were tested for total PSA, free PSA, and p2PSA. PHI was then calculated by using the formula, $[(p2PSA / fPSA) \times \sqrt{PSA}]$.

In addition, mpMRI at 1.5 or 3 T was performed in all patients. PHID was calculated by PHI divided by prostate volume on MRI. Reporting of mpMRI prostate was done according to PI-RADS version 2.0. All men in this study received transrectal or transperineal MRI-targeted and systematic biopsies.

Pathology reporting was performed according to The International Society of Urological Pathology (ISUP) Gleason grade group (GG). Clinically significant PCa was defined as ISUP GG 2 PCa.

Intervention Type

Other

Primary outcome(s)

Prostate cancer measured using the pathology report taken at a single time point.

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

31/12/2022

Eligibility**Key inclusion criteria**

Patients who were more than 40 years old and underwent MRI-targeted prostate biopsy for suspicious PCa due to elevated serum PSA level (PSA > 4 ng/mL)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

40 years

Upper age limit

70 years

Sex

Male

Total final enrolment

420

Key exclusion criteria

Prostate malignancy diagnosed before

Date of first enrolment

01/04/2016

Date of final enrolment

31/12/2022

Locations**Countries of recruitment**

Taiwan

Study participating centre**Taipei Veterans General Hospital**

No.201, Sec. 2, Shipai Rd., Beitou District

Taipei City

Taiwan

11217

Study participating centre**National Taiwan University Hospital**

No.1, Changde St., Zhongzheng Dist., 100229

Taipei City

Taiwan

100229

Study participating centre

China Medical University Hospital
No. 2, Yude Rd., North Dist.
Taichung City
Taiwan
404327

Sponsor information

Organisation

Taipei Veterans General Hospital

ROR

<https://ror.org/03ymy8z76>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

available on request (Dr. Ching-Hsin Chang, chinghsin.chang@gmail.com)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2024	17/07/2024	Yes	No