

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

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

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Screening

**Participant information sheet**

Not applicable (retrospective study)

**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 ( $PSA > 4 \text{ ng/mL}$ )

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  $\geq 2$  PCa.

**Intervention Type**

Other

**Primary outcome measure**

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

**Secondary outcome measures**

There are no secondary outcome measures

**Overall study start date**

01/04/2016

**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

**Age group**

Adult

**Lower age limit**

40 Years

**Upper age limit**

70 Years

**Sex**

Male

**Target number of participants**

450

**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

**Sponsor details**

No.201, Sec. 2, Shipai Rd., Beitou District  
Taipei City  
Taiwan  
11217  
+886-2-2875-7808  
imsc@vghtpe.gov.tw

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.vghtpe.gov.tw/>

**ROR**

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

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

02/03/2024

## 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?
<a href="#">Results article</a>		01/07/2024	17/07/2024	Yes	No