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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

Registration date
05/03/2024

Overall study status
Completed

Last Edited
17/07/2024

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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, jossp1029@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

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) X √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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes