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Assessing demographic, clinical and pathological determinants of advances prostate cancer in Indonesia for delayed diagnosis, treatment, and risk for secondary progression and survival

Submission date 14/10/2020	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 18/10/2020	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 16/10/2020	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims

The prostate is a small gland in the pelvis, found only in men. The causes of prostate cancer are largely unknown.

Several treatment options for patients range from active surveillance for less aggressive cancer to surgery and radiation for more advanced diseases. Androgen deprivation therapy (ADT) is an anti-hormone therapy for treating prostate cancer. But recently, tumors were identified that generally grow independent to the androgen hormone levels. This study aims to identify measures that can predict the outcome of ADT in Indonesian men.

Who can participate?

Patients aged 18 - 80 years old with a diagnosis of prostate cancer from 2017 to 2027

What does the study involve?

The study involves collecting information from patient records on the risk factors, course of the disease, the response to different treatments, recurrence rates, progression into other cancers, and death rates. There is an optional choice to provide a number of blood or tissue samples for the duration of diagnosis, treatment, and follow-up.

What are the possible benefits and risks of participating?

There are no specific risks or benefits to participants.

Where is the study run from?

Universitas Gadjah Mada / Dr Sardjito Hospital, Yogyakarta (Indonesia)

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

January 2017 to January 2027

Who is funding the study?
Universitas Gadjah Mada (Indonesia)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Surrogate biomarkers for Castration-resistant Prostate Cancer (CRPC): Indonesian population

Acronym
INA-BIOPRO

Study objectives
Surrogate Biomarker, Demographic, social, clinical, and pathological determinants are associated with delayed diagnosis, risks of relapse, and survival of Prostate Cancer diagnosed and treated according to the local and national guidelines in Indonesia. we downregulation TP53, RB1, PTEN and others associated RNA and MIR suggested predict the outcome of therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/04/2020, Ethics Committee of the Faculty of Medicine, Public Health, and Nursing - Universitas Gadjah Mada Yogyakarta (Jl. Farmako Sekip Utara, Yogyakarta 55281, Surabaya, 84311, Indonesia; +62 274 588688 ext 17225; mhrec_fmugm@ugm.ac.id), ref: KE/0158/02/2020

Study design
Observational cohort retrospective study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Biomarker predicting the outcome of Androgen Deprivation Therapies and Chemotherapies in Prostate Cancer patients

Interventions
All patients who underwent prostate biopsy were enrolled in this study.

The biopsied prostate cancer will be tested for several biomarkers. mRNA expression of targeted biomarkers are conducted using Real Time-Polymerase Chain Reaction (qRT-PCR) in Anatomical Pathology Laboratory of the Faculty of Medicine, Universitas Gadjah Mada, Yogyakarta. RNA purification from prostate tissue are conducted using RibospinTM II (GeneAll®) kit and NEXproTM 1-step qRT-PCR 2x Master Mix (SYBR) were used in this study. All of the procedures followed the manufacturer’s recommendations.

Clinical data are collected from medical records to evaluate the clinical features and confirmation of diagnosis.

The targeted gene is quantified using reverse transcription-polymerase chain reaction. For the relative quantification, the target gene expression is determined by the (2−ΔΔCt) method after normalization to the gene of GAPDH for CT values. RNA Isolation and cDNA Synthesis.

Patient outcome is evaluated each month on outpatients setting or inpatient setting.

Intervention Type
Not Specified

Primary outcome(s)
1. Time to achieve Castration resistant therapy (CRPC). CRPC is defined as castrate level of serum testosterone <50 ng/mL plus either
(i) biochemical progression – three consecutive rises of PSA, resulting in two 50% increases above the nadir value, with PSA >2 ng/mL, or
(ii) radiological progression – the appearance of two or more bone lesions on bone scan or enlargement of a soft tissue lesion based on RECIST criteria

Key secondary outcome(s))
1. Progression-free survival (PFS) measured using the methods described in the primary outcome measure at the end of the study

Completion date
01/01/2027

Eligibility

Key inclusion criteria
1. Diagnosed with advanced prostate cancer
2. Aged 18 - 80 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
18 years

Upper age limit
80 years

Sex
Male

Key exclusion criteria
1. Received systemic chemotherapy, targeted therapy, and immunomodulatory therapy prior study
2. Received local therapy including radical prostatectomy, radiotherapy, and other local therapy

Date of first enrolment
10/04/2020

Date of final enrolment
01/06/2025

Locations

Countries of recruitment
Indonesia

Study participating centre
RSUP Dr Sardjito Hospital
Jl. Kesehatan No.1
Senolowo
Sinduadi
Kec. Mlati
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Sponsor information

Organisation
Fakultas Kedokteran, Kesehatan Masyarakat dan Keperawatan UGM

Funder(s)

Funder type
University/education

Funder Name
Fakultas Kedokteran, Kesehatan Masyarakat dan Keperawatan UGM

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary

Available on request

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