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Assessing determinants of breast cancer patients in Indonesia for delayed diagnosis, treatment, risks of relapse, and survival

Submission date
29/09/2020

Recruitment status
Recruiting

Registration date
02/10/2020

Overall study status
Ongoing

Last Edited
08/06/2022

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Breast cancer is the most common cancer among women worldwide including in Indonesia. The death rates of breast cancer patients are significantly higher in developing countries including in Indonesia in comparison those in developed nations. The aim of this study is to collect a variety of data from patients diagnosed with breast cancer in order to define specific characteristics and recurrence rates, progression, and overall survival in breast cancer patients.

Who can participate?
Patients aged over 18 years old with a diagnosis of breast cancer from 2014 to 2022

What does the study involve?
The study involves collecting information on the risk factors, course of the disease, the response to different treatments, recurrence rates, progression, and death from cancer. 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 2018 to December 2026

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
INABrC01

Study information

Scientific Title
Assessing demographic, social, clinical, and pathological determinants of breast cancer patients for delayed diagnosis, treatment, risks of relapse, and survival

Acronym
INABrC

Study objectives

Demographic, social, clinical, and pathological determinants are associated with delayed diagnosis, risks of relapse, and survival of breast cancer diagnosed and treated according to the local and national guidelines in Indonesia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/10/2017, Ethics Committee of the Faculty of Medicine, Public Health, and Nursing (Universitas Gadjah Mada Yogyakarta, Jl Farmako Sekip Utara - Gedung Radiopetro 2nd Floor, Yogyakarta 55281, India; +62-274-588688-17225; mhrec_fmugm@ugm.ac.id), ref: 1143/EC/2017

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 available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Sociodemographic and clinicopathological determinants in breast cancer diagnosis and prognosis

Interventions
In this study, sociodemographic and clinicopathological variables will be collected and breast cancer patients will be followed-up for the locoregional recurrence, progression into distant metastasis, and survival.

The patient will be interviewed using a questionnaire (15-20 minutes to complete) to assess risks of breast cancer and general awareness of cancer and cancer screening. The patient will then be followed-up for minimum of 6 months. Medical records will be extracted to collect information of clinical and pathological variable including the follow-up examination according to the local clinical guidances (every 6 months examination of sonography, x-ray, and yearly mammography). A blood sample is optional if the patient agrees to donate for additional examination, 5-10 ml of whole blood will be taken and stored at the biobank.

Intervention Type
Other

Primary outcome measure

Overall survival at the end of the study measured using patient records

Secondary outcome measures
1. Sociodemographic backgrounds, occupation, income, general understanding of cancer, and hormonal factors such as menarche, menopause, BMI, contraception, number of children, breastfeeding practice, and usage of hormonal replacement therapy measured using a novel questionnaire at baseline
2. Cancer progression into distant metastasis, defined as presence of cancer spread to the lung, bone, liver, and brain indicating with clinical manifestations and were confirmed with imaging /pathology examination and/or radiologic changes confirmed with computed tomography imaging with contrast or whole-body bone scan every 6 months after baseline
3. Other clinical findings revealed by thorough clinical examination and imaging conducted at routine follow up visits retrieved from patient records

Overall study start date
06/01/2018

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Confirmed breast cancer according to the pathology report
2. Participants are able to provide written informed consent (over 18 years old)
3. No emergency procedure is required during the first presentation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
2,000

Key exclusion criteria
1. Vulnerable breast cancer patients

Date of first enrolment
06/04/2018

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Indonesia

Study participating centre
Universitas Gadjah Mada
Dr Sardjito Hospital
Jl Kesehatan No 1
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Sponsor information

Organisation
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Sponsor type
University/education

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Funder(s)

Funder type
University/education

Funder Name
Universitas Gadjah Mada

Funder Name
NUS-UGM-Tahir Foundation

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed international journal. Raw data without any identification of participants will be shared according to the WHO and ICMJE.

Intention to publish date
01/12/2026

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