

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

Submission date 29/09/2020	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 02/10/2020	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 08/06/2022	Condition category Cancer	☐ 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

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Observational

Study design

Observational cohort

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

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

Yogyakarta

Indonesia

55281

Sponsor information

Organisation

Universitas Gadjah Mada

Funder(s)**Funder type**

University/education

Funder Name

Universitas Gadjah Mada

Funder Name

NUS-UGM-Tahir Foundation

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