

The effect of moringa oleifera leaf extract on the inflammation status of breast cancer patients receiving hormonal therapy

Submission date 30/11/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/12/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/07/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In postmenopausal women who are positive for hormone receptors, an Aromatase Inhibitor (AI) to lower estrogen levels by stopping an enzyme in fat tissue (called aromatase) from changing other hormones into estrogen. Significant joint and muscular problems are frequently complained about and linked as side effects of AI therapy. The hands, wrists, and knees are the most commonly involved region in this illness also known as Aromatase Inhibitor - Associated Musculoskeletal Syndrome (AIMSS).

The aim of this study is to identify novel substances produced from medicinal plants and use them to develop analgesic and anti-inflammatory molecules.

Who can participate?

Breast cancer patients, post menopause, receiving an aromatase inhibitor and suffer from AIMSS.

What does the study involve?

Participants will be randomly allocated to receive the moringa oleifera leaf extract on a daily basis, or placebo for 30 days.

What are the possible benefits and risks of participating?

Benefits: Improvement from Aromatase Inhibitor - Associated Musculoskeletal Syndrome (AIMSS)

Risks: None

Where is the study run from?

Diponegoro University (Indonesia)

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

December 2021 to Spetember 2022

Who is funding the study?

Diponegoro University Research Fund (Indonesia)

Who is the main contact?

Dr Yan Wisnu, SpB(K)Onk, yanprajoko7519@gmail.com

Contact information

Type(s)

Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

The effect of moringa oleifera leaf extract on the inflammation status of breast cancer patients receiving aromatase inhibitor therapy

Study objectives

Moringa Oleifera leaf extract reduces inflammation status of breast cancer patients with estrogen receptor (+) and estrogen receptor (+) receiving Aromatase Inhibitor Therapy

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/05/2022, Dr Kariadi hospital research ethics committee (Jl. DR. Sutomo No.16, Randusari, Kec. Semarang Sel., Kota Semarang, Jawa Tengah 50244; +62 24 8413476; info@rskariadi.co.id), ref: 1126/EC/KEPK-RSDK/2022

Study design

Single center interventional double blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Moringa Oleifera leaf extract reduces inflammation status of breast cancer patients with estrogen receptor (+) and estrogen receptor (+) receiving Aromatase Inhibitor Therapy

Interventions

The research sample was divided into 2 groups: control and treatment groups.

The treatment group received a 300 mg capsule of Moringa leaf extract with a daily dose of 600 mg and diclofenac sodium 100 mg/day for analgesia, and the control group received a placebo capsule (2 capsules/day) and sodium diclofenac 100 mg/day for analgesia. Additionally, information was gathered on the subjects' ESR, CRP, CPK, and ANA levels. This information was collected from the subjects' medical records. Data on the levels of ESR, CRP, CPK, and ANA were gathered after the therapy was administered in accordance with the study group for 30 days.

Intervention Type

Supplement

Primary outcome measure

Inflammation status is measured using data on the levels of ESR, CRP, CPK, and ANA. Data is gathered pre-treatment and after treatment (30 days)

Secondary outcome measures

Measured using blood test:

1. Erythrocyte Sedimentation rate (ESR) measured at pre-treatment and after treatment (30 days)
2. C-Reactive Protein (CRP) measured at pre-treatment and after treatment (30 days)
3. Anti-Nuclear Antibody (ANA) measured at pre-treatment and after treatment (30 days)
4. Creatine Phosphokinase (CPK) measured at pre-treatment and after treatment (30 days)

Overall study start date

10/12/2021

Completion date

28/09/2022

Eligibility

Key inclusion criteria

1. Breast cancer patient
2. Post menopause
3. Immunohistochemistry Estrogen receptor (+), Progesterone receptor (+)
4. Received aromatase inhibitor
5. Patient with Aromatase Inhibitor-Associated Musculoskeletal Syndrome

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

70

Total final enrolment

78

Key exclusion criteria

1. Emergency condition that needs operation
2. Visceral metastasis
3. History of previous degenerative joint and soft tissue disease (osteoarthritis/rheumatoid arthritis).
4. History of fracture during the last 6 months

Date of first enrolment

01/06/2022

Date of final enrolment

28/08/2022

Locations**Countries of recruitment**

Indonesia

Study participating centre

Dr Kariadi hospital

Jl. Dr. Sutomo No. 16

Semarang

Jawa Tengah

Semarang

Indonesia

50244

Sponsor information**Organisation**

Diponegoro University

Sponsor details

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Sponsor type
University/education

Website
<https://fk.undip.ac.id>

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<https://ror.org/056bjta22>

Funder(s)

Funder type
University/education

Funder Name
Universitas Diponegoro

Alternative Name(s)
undip, Universitas Diponegoro (UNDIP, Universitas Diponegoro (UNDIP) (Semarang, Indonesia),
Universitas Diponegoro (UNDIP) Semarang, UNIVERSITAS DIPONEGORO The Excellent Research
University, Diponegoro University, UNDIP

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Indonesia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2023

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date