

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

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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)

Key secondary outcome(s)

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)

Completion date

28/09/2022

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

ROR

<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

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