

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

<b>Submission date</b> 30/11/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/12/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/07/2023	<b>Condition category</b> 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

## ClinicalTrials.gov (NCT)

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