ISRCTN11510869 https://doi.org/10.1186/ISRCTN11510869

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	[_] Prospectively registered [_] Protocol
Registration date 01/12/2022	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 19/07/2023	**Condition category** Cancer	[_] Individual participant data [_] 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. Imunohistokimia Estrogen receptor (+), Progesteron 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
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Sponsor information

Organisation
Diponegoro University

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Sponsor type
University/education

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

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

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