

Comparing turmeric and Indian frankincense extract with pain-relieving drugs for the treatment of osteoarthritis pain

Submission date 15/07/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/07/2019	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/09/2021	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Osteoarthritis is a long-lasting disease that results from the inflammation of the joints, causing breakdown of the cartilage and bone. Typically, a combination of exercise, lifestyle changes and non-steroidal anti-inflammatory (NSAID) drugs are used to reduce the pain and stiffness of osteoarthritis. NSAIDs can have side effects. Curcumin is a substance found in turmeric (*Curcuma longa*) that has been used to treat diseases involving inflammation in Ayurvedic (traditional Indian) and traditional Chinese medicine. Indian frankincense (*Boswellia serrata*) is another herb used to treat inflammation in Ayurvedic medicine. This study aims to investigate whether Biocurpain, a combination of turmeric and Indian frankincense extracts, can reduce pain in people with osteoarthritis.

Who can participate?

Adults who have been diagnosed with knee osteoarthritis for at least 4 weeks.

What does the study involve?

Participants will be randomly allocated to one of three groups. The first group will take Biocurpain and NSAID ibuprofen or diclofenac by mouth twice daily for 4 weeks. The second group will take Biocurpain by mouth twice daily for 4 weeks. The third group will take ibuprofen or diclofenac by mouth twice daily for 4 weeks. Before the start of the trial, at 2 weeks and at 4 weeks, the participants will rate their pain level on a scale of 1 to 10.

What are the possible benefits and risks of participating?

The potential benefits are that the participants might experience quicker relief from pain caused by osteoarthritis. The potential risks are that the participant might experience side effects from the study medication.

Where is the study run from?

Bethesda Hospital and Panti Rapih Hospital, Yogyakarta (Indonesia)

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

Who is funding the study?
Duta Wacana Christian University School of Medicine (Indonesia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2019/PZ/01

Study information

Scientific Title
The benefit and safety of Curcuma longa and Boswellia serrata for osteoarthritis pain

Acronym
Biocurpain

Study objectives
The combination of Curcuma longa and Boswellia serrata is as effective as NSAID treatment (ibuprofen or diclofenac) in treating arthritic pain with better safety profile.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 17/12/2018, Duta Wacana Christian University School of Medicine Ethical Research Committee, (Dr. Wahidin Sudirohusodo 5, 25 Yogyakarta, Indonesia 55224; 0274-563929 Ext. 124; kedokteranukdw@yahoo.com), ref: 867/C16/FK/2018

Study design

Randomized open-label clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Osteoarthritis

Interventions

This was a randomized controlled trial study for 4 weeks. Subjects were divided into 3 groups randomly:

1. Group I: combination of CB extract (Biocurpain; 350 mg of Curcuma longa and 150 mg Boswellia serrata) and NSAID (400 mg of ibuprofen or 50 mg of diclofenac sodium)
2. Group II: CB extract alone
3. Group III: NSAID alone.

Each medication was taken two times per day for 4 weeks. Twenty tablets of 500 mg paracetamol, as a rescue medication, was given to each subject and the remaining was counted at the last week. The degree of pain measured using visual analogue scale (VAS). Physician Global Assessment (PGA) was an instrument to measure the physicians' satisfaction with medication. Any adverse event was monitored. The analysis is intention to treat based.

Intervention Type

Supplement

Primary outcome(s)

Pain measured using a visual analogue scale (VAS) at baseline, 2 weeks and 4 weeks

Key secondary outcome(s)

Physicians' satisfaction with medication measured using the Physician Global Assessment (PGA) at 2 and 4 weeks

Completion date

01/08/2019

Eligibility

Key inclusion criteria

1. Aged 18 years or over
2. Diagnosed with osteoarthritis of the knee (Kellgren-Lawrence grade II or III) for at least 4 weeks

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

105

Key exclusion criteria

1. Not willing to join the study.
2. Subjects with known hypersensitivity to biocurpain ingredients and/or ibuprofen, diclofenac sodium or paracetamol
3. Participation in other clinical trial for the last 1 month
4. Significant renal, hepatic, gastrointestinal, and cardiovascular comorbidities
5. Pregnant or trying to become pregnant
6. Incompetent to give consent and answer the questionnaire
7. Received other pain treatment in 24 h before the study start

Date of first enrolment

01/03/2019

Date of final enrolment

01/07/2019

Locations**Countries of recruitment**

Indonesia

Study participating centre

Bethesda Hospital Yogyakarta

Jl Sudirman 70

Yogyakarta
Indonesia
55582

Sponsor information

Organisation

Duta Wacana Christian University School of Medicine

ROR

<https://ror.org/036agwg70>

Funder(s)

Funder type

University/education

Funder Name

Duta Wacana Christian University School of Medicine

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2019	09/09/2021	Yes	No