

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

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<b>Registration date</b> 24/07/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/09/2021	<b>Condition category</b> Musculoskeletal Diseases	<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 Chrstian University School of Medicine (Indonesia)

Who is the main contact?  
Dr. Rizaldy Taslim Pinzon, drpinzon17@gmail.com

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

No participant information sheet available.

### **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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

10/10/2018

## **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

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Both

## **Target number of participants**

100

## **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

### **Sponsor details**

Dr. Wahidin Sudirohusodo 5-25

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### **Sponsor type**

University/education

### **Website**

<https://www.ukdw.ac.id/en/academic/faculty-of-medicine/>

### **ROR**

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

## **Funder(s)**

### **Funder type**

University/education

### **Funder Name**

## Results and Publications

### Publication and dissemination plan

Publication in a peer-review journal.

### Intention to publish date

10/07/2019

### 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?
<a href="#">Results article</a>		01/11/2019	09/09/2021	Yes	No