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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

Registration date
24/07/2019

Overall study status
Completed

Last Edited
09/09/2021

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 Chrsitian 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
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Sponsor information

Organisation
Duta Wacana Christian University School of Medicine

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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?
Results article		01/11/2019	09/09/2021	Yes	No