ISRCTN10074826 https://doi.org/10.1186/ISRCTN10074826

# Clinical study to evaluate the efficacy and safety of curcumin, combination of curcumin and diclofenac in comparison with diclofenac alone in patients with osteoarthritis of the knee

**Submission date**
21/11/2017

**Recruitment status**
No longer recruiting

**Registration date**
29/11/2017

**Overall study status**
Completed

**Last Edited**
22/04/2020

**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 condition that causes joints to become painful and stiff and most commonly affects the joints of the hip, knee, hand, foot and spine. Osteoarthritis is not only the most common musculoskeletal disorder, affecting approximately 10% of the population worldwide, but more importantly is a leading cause of pain, loss of physical function, and reduction in health-related quality of life. Non-steroidal anti-inflammatory drugs (NSAIDs) are well established as first line treatment for chronic pain in osteoarthritis, providing effective relief of symptoms in most patients. However, NSAIDs causes gastrointestinal side effects like peptic ulcers, perforations, or bleeding. Supplments such as curcumin and diclofenac could be helpful to relieve the symptoms. The aim of this study is to evaluate the efficacy and safety of curcumin, combination of curcumin and diclofenac in comparison with diclofenac alone in patients with osteoarthritis of the knee.

Who can participate?
Adults aged 38 to 65 who have osteoarthritis in at least one knee joint.

What does the study involve?
The patients are randomly allocated to one of three groups. Those in the first group receive Curcumin 500 mg thrice daily for 28 days. Those in the second group received Curcumin 500 mg plus diclofenac 50 mg twice daily for 28 days. Those in the third group receive Diclofenac 50 mg twice daily for 28 days. Participants are followed up to examine the efficacy of the medications.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in their symptoms. Participation in the study is voluntary and no risk is associated with it. Patients can refuse to participate or withdraw at any time without it affecting their treatment. All information obtained for this study is used for research purposes only and will be kept strictly confidential.

Where is the study run from?
City Care Accident Hospital, ParliVaijanth (India)

When is the study starting and how long is it expected to run for?
July 2010 to January 2013

Who is funding the study?
City Care Accident Hospital, ParliVaijanth (India)

Who is the main contact?
Mr. D M Shep
dhaneshshep@gmail.com

# Contact information

### Type(s)
Scientific

### Contact name
Mr D. M. Shep

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Krishna Institute of Medical Sciences University
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# Additional identifiers

### Protocol serial number
CT240910 Version 2

# Study information

### Scientific Title
A randomized, single-blind, comparative, clinical study to evaluate theefficacy and safety of curcumin, combination of curcumin and diclofenac in comparison with diclofenac alone in patients with osteoarthritis of the knee

### Study objectives
The aim of this study is evaluate the efficacy and safety of curcumin, combination of curcumin and diclofenac in comparison with diclofenac alone in patients with osteoarthritis of the knee

### Ethics approval required
Old ethics approval format

### Ethics approval(s)

Institutional ethics committee, Krishna Institute of Medical Sciences, 20/10/2010, ref: kimsu/PhD /11/2010

## Primary study design
Interventional

## Study design
Randomised single-blind comparative clinical study

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Osteoarthritis

## Interventions
Participants are randomized into three groups – Group A, Group B and Group C by using a computer generated randomization sheet.
Group A: Participants receive Curcumin 500 mg thrice daily (taken orally) for 28 days.
Group B: Participants receive Curcumin 500 mg plus diclofenac 50 mg twice daily (taken orally) for 28 days
Group C: Participant receive Diclofenac 50 mg twice daily (taken orally)for 28 days.

At the time of enrollment, study & rescue medications were dispensed to the enrolled patients as per randomization. Patients are told to keep the record as per instructions and were told to come for two follow up visits (at the end of 2nd week and at the end of 4th week).

## Intervention Type
Supplement

## Primary outcome(s)
1. Efficacy of curcumin in comparison with diclofenac in the management of osteoarthritis of the knee is measured using Visual analogue scale and KOOS (Knee injury and Osteoarthritis Outcome Score) at day 14 and day 28
2. Efficacy of combination of curcumin & diclofenac in comparison with diclofenac alone in the management of osteoarthritis of the knee is measured usingVisual analogue scale and KOOS (Knee injury and Osteoarthritis Outcome Score) at day 14 and day 28

## Key secondary outcome(s)
1. Anti-ulcer effect of curcumin is measured by counting number of H2 blockers consumed by Curcumin and Diclofenac group at day 28
2. Effect of curcumin on protection against diclofenac induced GI side effects is measured by comparing GI Side effects between Group B received Curcumin 500 mg Capsule plus diclofenac 50 mg Tab andGroup C received Diclofenac 50 mg Tab at Day 28
3. Antiflatulent effect of curcumin by measuringchange in number of episodes of flatulence from baseline at day 14
4. Safety of curcumin/diclofenac by measuringside effects at day 14 and day 28
5. Safety of combination of curcumin and diclofenac by measuring side effects at day 14 and day 28

## Completion date

15/01/2013

# Eligibility

### Key inclusion criteria
1. Subjects of both sexes between 38 and 65 years of age
2. OA in at least one knee joint (ACR classification for knee OA) confirmed by X ray
3. A minimum pain VAS score > 4 on walking in one or both knees during the 24 hours preceding recruitment
4. Duration – minimum 3 months to 2 years with no joint deformities
5. Patient ambulant and requiring treatment with anti- inflammatory drugs
6. Patient willing to give washout period of 3-7 days
7. Patient willing to give written informed consent and willing to comply with the trial protocol
8. Patients with knee osteoarthritis.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Sex
All

### Total final enrolment
139

### Key exclusion criteria
There is no exclusion criteria.

### Date of first enrolment
27/02/2011

### Date of final enrolment
11/11/2012

# Locations

### Countries of recruitment
India

### Study participating centre

**City Care Accident Hospital**
ParliVaijanth
India
431515

# Sponsor information

**Organisation**
City Care Accident Hospital

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
City Care Accident Hospital

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are/will be available upon request from D M Shep dhaneshshep@gmail.com

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 11/04/2019 | 15/04/2019 | Yes | No |
| Results article | results | 01/04/2020 | 22/04/2020 | Yes | No |