

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/11/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 22/04/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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. Supplements 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
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Contact information

Type(s)
Scientific

Contact name
Mr D. M. Shep

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CT240910 Version 2

Study information

Scientific Title
A randomized, single-blind, comparative, 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

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

Study design

Randomised single-blind comparative clinical study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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 using Visual analogue scale and KOOS (Knee injury and Osteoarthritis Outcome Score) at day 14 and day 28

Secondary outcome measures

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 and Group C received Diclofenac 50 mg Tab at Day 28
3. Antiflatulent effect of curcumin by measuring change in number of episodes of flatulence from baseline at day 14
4. Safety of curcumin/diclofenac by measuring side 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

Overall study start date

12/07/2010

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

Age group

Mixed

Sex

Both

Target number of participants

210

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

Sponsor details

City Care Accident Hospital

Maniknagar

ParliVaijanth

India

431515

Sponsor type

Hospital/treatment centre

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

City Care Accident Hospital

Results and Publications

Publication and dissemination plan

Planned publication of the results in a high-impact peer-reviewed journal. First publication expected to be submitted before January 2018. Study protocol available on request.

Intention to publish date

31/01/2018

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