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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
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Contact information

Type(s)
Scientific

Contact name
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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

Study design
Randomised single-blind comparative clinical study

Primary study design
Interventional

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