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Comparative efficacy of Boswellia serrata extract and 5-Loxin® in the treatment of osteoarthritis of knee: a randomised, double-blind placebo-controlled clinical study

Submission date
13/09/2008

Recruitment status
No longer recruiting

Registration date
09/10/2008

Overall study status
Completed

Last Edited
09/10/2008

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Protocol serial number
08-001/5-Lo, BE/OA

Study information

Scientific Title

Study objectives
Boswellia serrata extract have been proven to be effective against inflammatory disorders in clinical trials, but no comparative clinical investigation has been carried out to demonstrate the efficacy and underlying mechanistic pathways involved therein. Furthermore, a broad spectrum of studies have evidenced that non-steroidal anti-inflammatory drugs (NSAIDs) induce painful gastrointestinal irritation as well as bleeding. No such adverse effects have been reported for natural Boswellia products.

In recent past, we have developed and proved clinical efficacy of a novel Boswellia serrata extract (5-Loxin®) enriched with 30% acetyl-11-keto-beta boswellic acid (AKBA) (Pending US patent [ref: 2004/0073060A1], Indian patent [ref: 205269], Australian patent [2002242934]). In a published clinical study (http://www.ncbi.nlm.nih.gov/pubmed/18667054; registered with ISRCTN05212803), we have shown that oral administration of 5-Loxin® conferred significant improvement in clinical signs and symptoms of patients with osteoarthristis (OA) of knee. This study also suggests that 5-Loxin® can normalise the elevated Matrix metalloproteinase-3 enzyme in synovial fluid which helps to reduce the cartilage degradation in OA.

However, till date no clinical study has been reported the comparative efficacy of 5-Loxin® and Boswellia serrata extract in OA. Therefore, in the present clinical study we designed to assess comparative efficacy of 5-Loxin® with Boswellia serrata extract (BE) against OA of knee.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This protocol was approved by the Institutional Review Board of Alluri Sitarama Raju Academy of Medical Sciences (ASRAM) on 16/07/2008 (ref: 08-001 / 5-LO, BE/OA).

Study design
Randomised placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis of knee

Interventions
75 subjects randomised into 3 groups (n = 25):
1. 5-Loxin® (oral), 50 mg twice daily (bid)
2. Boswellia extract (oral), 500 mg bid
3. Placebo

Ibuprofen was used as a rescue medication for all groups. The study duration is 90 days and evaluations are at baseline, 7, 30, 60 and 90 days.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Boswellia serrata extract (5-Loxin®)

Primary outcome(s)
1. Pain, assessed with VAS
2. LFI
3. Western Ontario and McMaster Universities osteoarthritis index (WOMAC)-pain, WOMAC-stiffness and WOMAC-physical ability

All primary outcomes will be measured at baseline, 7, 30, 60 and 90 days of the study.

Key secondary outcome(s))
1. C-Reactive Protein (CRP)
1. Matrix Metelloproteinase-3 (MMP-3)

The secondary outcomes will be measured at baseline, 7, 30, 60 and 90 days of the study.

Completion date
14/12/2008

Eligibility

Key inclusion criteria
1. Participants must understand risks and benefits of the protocol and able to give informed consent
2. Male and female subjects of 40-80 years of age
3. Females of child bearing potential must agree to use an approved form of birth control and have a negative pregnancy test result
4. Unilateral or bilateral OA of the knee for more than 3 months
5. Visual Analogue Scale (VAS) score during the most painful knee movement between 40-70 mm after 7 day withdrawal of usual medication
6. Lequesne's Functional Index (LFI) score greater than 7 points after 7 days of withdrawal of usual medication
7. Ability to walk
8. Availability for the duration of the entire study period

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. History of underlying inflammatory arthropathy or severe rheumatoid arthritis (RA)
2. Hyperuricemia (greater than 440 umol/L) and/or past history of gout
3. Recent injury in the area affected by OA of the knee (past 4 months) and expectation of surgery in the next 4 months
4. Intra-articular corticosteroid injections within the last 3 months
5. Hypersensitivity to NSAIDs, abnormal liver or kidney function tests, history of peptic ulceration and upper gastrointestinal (GI) haemorrhage, congestive heart failure, hypertension, hyperkalemia
6. Major abnormal findings on complete blood count, history of coagulopathies, haematological or neurological disorders
7. High alcohol intake (greater than 2 standard drinks per day)
8. Pregnant, breastfeeding or planning to become pregnant during the study
9. Use of concomitant prohibited medication other than ibuprofen
10. Obesity: Body Mass Index (BMI) more than 30

Date of first enrolment
15/09/2008

Date of final enrolment
14/12/2008

Locations

Countries of recruitment
India

Study participating centre
Department of Orthopaedics
Eluru
India
534 002

Sponsor information

Organisation
Laila Impex (India)

ROR
https://ror.org/05q6g7072

Funder(s)

Funder type
Industry

Funder Name
Laila Impex (India)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration