

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	☐ Prospectively registered
Registration date 09/10/2008	Overall study status Completed	☐ Protocol
Last Edited 09/10/2008	Condition category Musculoskeletal Diseases	☐ 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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Additional identifiers

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 osteoarthritis (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 Metalloproteinase-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