

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

<b>Submission date</b> 13/09/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 09/10/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/10/2008	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

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

### **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 measure**

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.

### **Secondary outcome measures**

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.

### **Overall study start date**

15/09/2008

### **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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

75

**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)

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R&D Center  
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**Sponsor type**  
Industry

**Website**  
<http://lailaimpex.tradeindia.com>

**ROR**  
<https://ror.org/05q6g7072>

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
Laila Impex (India)

## **Results and Publications**

**Publication and dissemination plan**  
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration