# Comparative efficacy of 5-Loxin® and its improved composition (5-Loxin®BSO) in the treatment of osteoarthritis of knee: a randomised, double-blind placebo-controlled clinical study

Recruitment status  No longer recruiting	Prospectively registered	
	☐ Protocol	
Overall study status	Statistical analysis plan	
Completed	[X] Results	
Condition category	[] Individual participant data	
	No longer recruiting  Overall study status  Completed	

# Plain English summary of protocol

Not provided at time of registration

### Contact information

## Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers

08-002/5-Loxin+/OA

# Study information

### Scientific Title

Comparative efficacy of 5-Loxin® and its improved composition (5-Loxin®BSO) in the treatment of osteoarthritis of knee: a randomised, double-blind placebo-controlled clinical study

### **Study objectives**

The purpose of this study is to assess the comparative efficacy of 5-Loxin® and an improved novel composition of 5-Loxin® (5-Loxin® BSO) against osteoarthritis (OA) and pain management, which represent a challenge to the health professionals.

Results of a related study can be found at: http://www.ncbi.nlm.nih.gov/pubmed/18667054 (this trial is registered with ISRCTN05212803).

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

This protocol was approved by the Institutional Review Board (IRB) of Alluri Sitarama Raju Academy of Medical Sciences (ASRAM) on the 16th July 2008.

### 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**

60 subjects randomised into 3 groups (n = 20):

- 1. 5-Loxin® (oral) 50 mg twice daily (bid)
- 2. 5-Loxin®-BSO (oral) 50 mg bid
- 3. Placebo

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

### Intervention Type

Drug

### Phase

**Not Specified** 

### Drug/device/biological/vaccine name(s)

5-Loxin®, 5-Loxin® BSO

### Primary outcome measure

- 1. Pain, assessed by 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)
- 2. Matrix Metelloproteinase-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. Leguesne'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

60

### Total final enrolment

60

### 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 non-steroidal anti-inflammatory drugs (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

# Sponsor information

### Organisation

Laila Impex (India)

### Sponsor details

R&D Centre Unit 1 Phase III Jawahar Autonagar Vijayawada India 520007 +91 866 254 5244 lailarescen@sify.com

### 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

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2010	30/12/2020	Yes	No