

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

Submission date

13/09/2008

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

09/10/2008

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

30/12/2020

Condition category

Musculoskeletal Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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.

Primary study design

Interventional

Study design

Randomised placebo-controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

1. C-Reactive Protein (CRP)
2. 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

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

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

Study outputs

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