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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	Recruitment status	[_] Prospectively registered
13/09/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/10/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/12/2020	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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. 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
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

India
534 002

Sponsor information

Organisation
Laila Impex (India)

Sponsor details
R&D Centre
Unit 1 Phase III
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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

Study outputs

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