ISRCTN69643551 https://doi.org/10.1186/ISRCTN69643551

Efficacy of Aflapin® in the treatment of osteoarthritis of knee

Submission date	Recruitment status	[_] Prospectively registered
05/09/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/02/2012	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
09-002/Aflapin®/OA

Study information

Scientific Title

Efficacy of Aflapin® in the treatment of osteoarthritis of knee: a randomised, double-blind placebo controlled clinical study

Study objectives
Aflapin® is an improved novel composition of Boswellia serrata extract standardised to 30% 3-O-acetyl-11-keto-beta-boswellic acid (BE-30). Pre-clinical studies demonstrate that Aflapin® is up to 25% more bioavailable than BE-30. Therefore, we hypothesise that Aflapin® would provide faster relief form clinical symptoms of osteoarthritis (OA).

Results of a related study with BE-30 against osteoarthritis 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)
Institutional Review Board (IRB) of Alluri Sitarama Raju Academy of Medical Sciences (ASRAM) approved on the 1st August 2009.

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

Interventions
60 subjects randomised into 2 groups (n = 30):
1. Aflapin® (oral) 50 mg twice daily (bid)
2. Placebo

Ibuprofen will be used as a rescue medication for both groups. The study duration is 30 days and evaluations will be at baseline, 5, 15 and 30 days.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Aflapin®

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

Measured at baseline, 5, 15 and 30 days of the study.

Secondary outcome measures
1. Tumor necrosis factor alpha (TNFa)
2. C-reactive protein (CRP)
3. Matrix metelloproteinase-3 (MMP-3)

Measured at baseline, 5, 15 and 30 days of the study.

Overall study start date
01/09/2009

Completion date
01/11/2009

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
Sixty (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 kg/m^2

Date of first enrolment
01/09/2009

Date of final enrolment
01/11/2009

Locations

Countries of recruitment
India

Study participating centre
Department of Orthopaedics
Eluru
India
534 002

Sponsor information

Organisation
Laila Impex R&D Center (India)

Sponsor details

Unit 1 Phase III
Jawahar Autonagar
Vijayawada
India
520007

Sponsor type
Industry

Website
http://lailaimpex.tradeindia.com/

ROR
https://ror.org/05q6g7072

Funder(s)

Funder type
Industry

Funder Name
Laila Impex R&D Center (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	01/11/2011		Yes	No