

# Efficacy of Aflapin® in the treatment of osteoarthritis of knee

<b>Submission date</b> 05/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 06/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/02/2012	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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 from 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

### **Study type(s)**

Treatment

### **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(s)**

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.

**Key secondary outcome(s))**

1. Tumor necrosis factor alpha (TNFa)
2. C-reactive protein (CRP)
3. Matrix metalloproteinase-3 (MMP-3)

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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<sup>2</sup>

**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)

**ROR**

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

## Funder(s)

**Funder type**

Industry

**Funder Name**

Laila Impex R&D Center (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?
<a href="#">Results article</a>	results	01/11/2011		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes