

# Safety and Efficacy of Loxoprofen Sodium cataplasm Ointment Against Knee Osteoarthritis

<b>Submission date</b> 15/11/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 13/12/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 15/06/2017	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Knee arthrosis occurs when the protective layer around the knee is damaged due to wear and tear, causing the bones to rub against each other. This causes pain and stiffness. There are a number of different treatment methods, such as taking anti-inflammatory (swelling) medications for pain relief. The medication can come in an ointment or in a tablet to be taken by mouth. However, taking tablets by mouth can injury the digestive area, liver and kidneys. Using ointment may be a better option. The aim of this study is to compare the results of taking an anti-inflammatory medication called Loxoprofen Sodium Cataplasm as either an ointment or a tablet for the treatment of knee osteoarthritis.

### Who can participate?

Patients aged between 18 and 80 years Knee osteoarthritis

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive the treatment as an ointment that they apply once a day and a placebo (dummy) tablet three times a day. Those in the second group receive a placebo ointment and the medication as a tablet that is taken three times a day. This is done for four weeks. Participants are followed up to see if their symptoms have improved.

### What are the possible benefits and risks of participating?

After you participate this study, you can get better treatment for the knee osteoarthritis. At the same time, there exist some risks. The study drug may induce the drug adverse events. These drug adverse events may occur on you or not.

### Where is the study run from?

Peking University and People's Hospital (China)

### When is study starting and how long is it expected to run for?

July 2010 to February 2012

Who is funding the study?  
Lead Chemical Co. Ltd (Japan)

Who is the main contact?  
Professor Rong Mu  
murongster@gmail.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Zhan-guo Li

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
YXCS-01-LOX

## Study information

**Scientific Title**  
A randomized, controlled, double blind, double dummy clinical trial to evaluate the safety and efficacy of Loxoprofen Sodium Cataplasma Ointment (Loxonin®PAP100mg) against knee osteoarthritis

**Acronym**  
SELSOAKO

**Study objectives**  
There will be non-inferiority between Loxoprofen Sodium Cataplasma Ointment and its tablet formulation for the treatment of knee osteoarthritis.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Central Ethic Committee of Peking University People's Hospital, 27 July 2010 ref: 35

**Study design**

Randomized controlled double blind double dummy study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please contact murongster@gmail.com to request a patient information sheet

**Health condition(s) or problem(s) studied**

Knee osteoarthritis

**Interventions**

Study group: Loxoprofen Sodium Cataplasm ointment one time each day, one patch each time (100 mg) + placebo tablet 3 times a day, 1 tablet each time (60 mg)

Control group: Placebo Cataplasm ointment one time each day, one patch each time (100 mg) + Loxoprofen Sodium tablet 3 times a day, 1 tablet each time (60 mg)

Administration duration is 4 weeks, and the prescription is changed for every 2 weeks.

**Intervention Type**

Drug

**Phase**

Not Specified

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

Loxoprofen

**Primary outcome measure**

Total effective rates after 4 weeks treatment

1. Apparently improved
2. Improved
3. Slightly improved
4. Unchanged

5. Slightly aggravated
6. Aggravated
7. Significantly aggravated

**Secondary outcome measures**

Effective rates against different symptoms

**Overall study start date**

27/07/2010

**Completion date**

10/02/2012

## Eligibility

**Key inclusion criteria**

1. Age: > 18 years, < 80 years
2. Sex: unrestricted
3. Patients conforming to clinical diagnostic criteria
4. Patients agree to participate this trial and sign informed content form after completely understanding the contents of the clinical trial

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

80 Years

**Sex**

Both

**Target number of participants**

160

**Key exclusion criteria**

1. Patients with digestive ulcers
2. Patients with bronchial asthma
3. Patients with serious cardiac diseases, hepatic diseases (ALT, AST are equal or bigger than 2.5 times of upper limit), renal diseases (creatinine is equal or bigger than 1.5 times of upper limit), hematologic disease, diabetes, mental diseases, and other serious complications
4. Pregnant women, lactating women, patients with pregnancy potential, and patients who want to be pregnant during the clinical trial
5. Patients with drug hypersensitivity (aspirin asthma, hypersensitive to loxoprofen sodium or other drugs)

6. Patients with lesions, poor skin conditions on pasting site, or with cutaneous anaphylaxis (dermatitis due to external agent or patients with dermatitis)
7. Patients combining other rheumatic diseases
8. Patients who need steroid drugs or other non-steroid analgesics which may interfere the therapeutic method in this clinical trial
9. Patients participating any clinical trials on investigational drug or marketing drug within 3 months before inclusion or during clinical trial
10. Other patients judged to be inappropriate for this clinical trial by the investigator

**Date of first enrolment**

27/07/2010

**Date of final enrolment**

10/02/2012

## **Locations**

**Countries of recruitment**

China

**Study participating centre**

**People's Hospital**

Bei Jing

China

100044

## **Sponsor information**

**Organisation**

Lead Chemical Co. Ltd (Japan)

**Sponsor details**

77-3 Himata

Toyama

Japan

930-0912

**Sponsor type**

Industry

**Website**

<http://www.lead-chemical.co.jp>

**ROR**

<https://ror.org/02bexj159>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

Lead Chemical Co. Ltd (Japan)

## **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