

Safety and Efficacy of Loxoprofen Sodium cataplasm Ointment Against Knee Osteoarthritis

Submission date 15/11/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 13/12/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/06/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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 injure 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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 Cataplastm Ointment (Loxonin®PAP100mg) against knee osteoarthritis

Acronym
SELSOAKO

Study objectives
There will be non-inferiority between Loxoprofen Sodium Cataplastm Ointment and its tablet fomuration 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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Knee osteoarthritis

Interventions

Study group: Loxoprofen Sodium Cataplast 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 Cataplast 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(s)

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

Key secondary outcome(s)

Effective rates against different symptoms

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

All

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)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Lead Chemical Co. Ltd (Japan)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration