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Safety and Efficacy of Loxoprofen Sodium cataplasm Ointment Against Knee Osteoarthritis

Submission date
15/11/2012

Recruitment status
No longer recruiting

Registration date
13/12/2012

Overall study status
Completed

Last Edited
15/06/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 tabulets 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
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Contact information

Type(s)
Scientific

Contact name
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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 Cataplasm Ointment (Loxonin®PAP100mg) against knee osteoarthritis

Acronym
SELSOAKO

Study objectives
There will be non-inferiority between Loxoprofen Sodium Cataplasm 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

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