ISRCTN16227145 https://doi.org/10.1186/ISRCTN16227145

Safety and Efficacy of Loxoprofen Sodium cataplasm Ointment Against Myalgia (SELSOAM)

Submission date
03/07/2014

Recruitment status
No longer recruiting

Registration date
29/12/2014

Overall study status
Completed

Last Edited
07/02/2019

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Loxonin (loxoprofen sodium) is a kind of non-steroidal anti-inflammatory drug (NSAID). Loxonin tablets are widely used as a painkiller or anti-inflammatory, but like other NSAIDs, they have a number of side effects or adverse reactions (ADR's). These may include heartburn, headaches, nausea, gastrointestinal problems (such as constipation or diarrhoea) and even intestinal or stomach ulcers. A Loxonin ointment, designed to be applied externally to the skin has therefore been developed in order to reduce the risk of ADR's when taking the medication. Loxonin is widely used for myalgia (muscle pain). This study aims to compare the effectiveness and safety of the Loxonin ointment with Loxonin tablets for the treatment of myalgia.

Who can participate?
Patients aged 18 to 80 with moderate muscle pain on resting, pressing on the affected muscle or when exercising.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 (the study group) are treated with the Loxonin ointment once a day and a placebo (dummy) tablet three times a day. Those in group 2 (the control group) are treated with a placebo ointment once a day and a loxoprofen sodium tablet three times a day.

What are the possible benefits and risks of participating?
This product has been marketed in Japan for many years and as it's an external application it's relatively safe. Participants will receive the treatment for free and given appropriate economic compensation.

Where is the study run from?
1. Peking University People's Hospital (China)
2. Beijing ChaoYang Hospital (China)
3. China-Japan Friendship Hospital (China)
4. The 1st Hospital of Harbin Medical University (China)

5. The 1st Hospital of China Medical University (China)
6. Shanghai Changhai Hospital (China)
7. The 1st Hospital of SuZhou University (China)
8. Union Hospital TongJi Medical College HuaZhong University of Science and Technology, Rheumatism department (China)
9. Union Hospital TongJi Medical College HuaZhong University of Science and Technology, Orthopaedics department (China)

When is the study starting and how long is it expected to run for?
November 2010 to August 2011.

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

Who is the main contact?
Prof Zhanguo Li

Contact information

Type(s)
Scientific

Contact name
Prof Zhanguo Li

Contact details
Peking University People's Hospital
No. 11 South Xizhimen Street
Beijing
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100044

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
YXCS-02-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 myalgia

Acronym

SELSOAM

Study objectives
There will be non-inferiority between Loxoprofen Sodium Cataplasm Ointment and its tablet formulation for the treatment of myalgia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Ethics Committee of Peking University People's Hospital, 27/07/2010

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 use the contact details below to request a patient information sheet

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

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

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

Duration of administration is 2 weeks, and the prescription is changed for every 1 week.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Loxoprofen Sodium

Primary outcome measure
Physical test, including the following four symptoms (rest pain, pressing pain, exercising pain, limited movement); each symptom has four grades: no effect, slightly, median, heavily.
Timepoint: measured at baseline, 1 week after treatment, 2 weeks after treatment

Secondary outcome measures
Effective rates against different symptoms

Overall study start date
18/11/2010

Completion date
24/08/2011

Eligibility

Key inclusion criteria
1. Age: > 18 years, < 80 years, 18 and 80 years included
2. Either sex
3. Any of the following with moderate intensity: resting pain, pressing pain, exercising pain
4. The patients were not treated by drugs for one week before giving the investigational product, and no change in physiotherapy for 2 weeks during the first treatment.
5. Patients agree to participate in the 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

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Patient's pain caused by external injury and diagnosed as acute
2. Patient's pain diagnosed as neurosis
3. Patients with lesions, poor skin conditions on pasting site, or with cutaneous anaphylaxis
4. Patients who need steroid drugs or other non-steroid analgesics which may interfere the therapeutic method in this clinical trial.
5. Patient with peptic ulcer.
6. Patients with bronchial asthma.

7. 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.
8. Pregnant women, lactating mothers or patients who have the possibility of pregnancy, and want to be pregnant during the trial.
9. Patient allergic to this drug.
10. Patients participating any clinical trials on investigational drug or marketed drug within 3 months before enrollment or during clinical trial
11. Other patients judged to be inappropriate for this clinical trial by the investigator

Date of first enrolment
18/11/2010

Date of final enrolment
24/08/2011

Locations

Countries of recruitment
China

Study participating centre
Peking University People's Hospital
Beijing
China
-

Study participating centre
Beijing ChaoYang Hospital
Beijing
China
-

Study participating centre
China-Japan Friendship Hospital
Beijing
China
-

Study participating centre

The 1st Hospital of Harbin Medical University
Harbin
China
-

Study participating centre
The 1st Hospital of China Medical University
Shenyang
China
-

Study participating centre
Shanghai Changhai Hospital
Shanghai
China
-

Study participating centre
The 1st Hospital of SuZhou University
SuZhou
China
-

Study participating centre
Union Hospital, TongJi Medical College, HuaZhong University of Science and Technology, rheumatism department
Wuhan
China
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Study participating centre
Union Hospital, TongJi Medical College, HuaZhong University of Science and Technology, orthopaedics department
Wuhan
China
-

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
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2019		Yes	No