ISRCTN10182003 https://doi.org/10.1186/ISRCTN10182003

Safety and Efficacy of Loxoprofen Sodium cataplasm Ointment Against Swelling and Pain caused By Trauma (SELSOASPBT)

Submission date 03/07/2014	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 29/12/2014	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 29/12/2014	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] Record updated in last year

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 swelling and inflammation caused by injuries. This study aims to compare the effectiveness and safety of Loxonin ointment with Loxonin tablets.

Who can participate?
Patients aged 18 to 80 diagnosed with a traumatic sprain or wound, within 5 days of injury, with at least one of the following: resting pain, pressing pain, exercising pain and symptoms of inflammation (swelling and local burning) considered as more than mild.

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. China-Japan Friendship Hospital (China)
3. The 1st Hospital of Harbin Medical University (China)

4. The 1st Hospital of China Medical University (China)
5. Shanghai Changhai Hospital (China)
6. Beijing JiShuiTan Hospital (China)
7. Union Hospital TongJi Medical College HuaZhong University of Science and Technology (China)

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
YXCS-03-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 swelling and pain caused by trauma

Acronym
SELSOASPBT

Study objectives
There will be non-inferiority between Loxoprofen Sodium Cataplasm Ointment and its tablet fomuration 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
Swelling and pain caused by trauma

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: 7 days.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Loxoprofen Sodium

Primary outcome measure
Physical test, including the following three items: pain (rest pain, rest pain, pressing pain, exercising pain), symptoms of inflammation (swelling, topical burning), limited movement. Timepoint: measured at baseline, 3 days after treatment, 7 days after treatment

Secondary outcome measures
Effective rates of different symptoms

Overall study start date
09/12/2010

Completion date
15/08/2011

Eligibility

Key inclusion criteria
1. Age: > 18 years, < 80 years, 18 and 80 years included
2. Either sex
3. Patients diagnosed with traumatic sprain, wound etc. within 5 days of injury
4. Patients with at least one of the following: resting pain, pressing pain, exercising pain and inflammation symptoms (swelling and local burning) considered as more than mild.
5. Patients not treated with drugs for this for 5 days before this trial.
6. 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. Patients injured over 6 days.
2. Patients with bacterial infections.
3. Patients with fractures, plaster casts or need surgery.
4. Patients with neck sprain (head tremor).
5. Patient with small pasting site (like fingers) could not use the patch.
6. Patients with lesions, poor skin conditions on pasting site, or with cutaneous anaphylaxis.
7. Patients who need steroid drugs or other non-steroid analgesics which may interfere the therapeutic method in this clinical trial.

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

Date of first enrolment
09/12/2010

Date of final enrolment
15/08/2011

Locations

Countries of recruitment
China

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

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

Sponsor information

Organisation
Lead Chemical Co. Ltd (Japan)

Sponsor details
77-3 Himata
Toyama
Japan
930-0912

Sponsor type
Industry

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