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Clinical trial to evaluate the safety and efficacy of a diclofenac epolamine (DHEP) plaster in minor soft tissue injuries

Submission date
04/03/2013

Recruitment status
No longer recruiting

Registration date
19/03/2013

Overall study status
Completed

Last Edited
19/03/2013

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A DHEP medicated plaster contains 180 mg of a diclofenac salt, named diclofenac epolamine or DHEP, and it allows a continuous release of the drug from the plaster during the application period. This plaster has been marketed by many years in Europe and USA for the local treatment of pain and inflammation of traumatic and rheumatic origin. Our goal was to demonstrate how well the DHEP plaster works for the treatment of minor soft tissue injuries in the Chinese population.

Who can participate?
Adult male and female patients (18-65 years) with a minor soft tissue injury, such as ankle or knee joint sprain, muscle strain or contusion, which has occurred within the last 72 hours.

What does the study involve?
Participants were randomly allocated to one of two groups. One group of patients applied two DHEP plasters per day, each for 12 hours, for 7 days. The other group applied a placebo (dummy) plaster instead. During the study the severity of pain was measured using an established scale. The safety was also assessed by blood and urinalysis at the beginning and at the end of the study.

What are the possible benefits and risks of participating?
The participants who received the DHEP plaster can expect an improvement of their pain symptoms. The most common side effects seen with DHEP plasters are skin reactions (including itching, inflamed skin, burning) at the site of treatment.

Where is the study run from?
From 10 medical centres in China, with Peking University First Hospital in Beijing as lead centre.

When is the study starting and how long is it expected to run for?
The study started in April 2010 and ended in November 2010 when the required number of 384 patients (192 for each group) was recruited and treated.

Who is funding the study?
IBSA Institut Biochimique (Switzerland)

Who is the main contact?
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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
09RC-Fp14

Study information

Scientific Title
A multicentre, randomised, double-blind, placebo-controlled confirmatory clinical trial of the efficacy and safety of diclofenac epolamine medicated plaster in the treatment of minor soft tissue injuries

Study objectives
To evaluate the efficacy and safety of DHEP medicated plaster for the treatment of minor soft tissue injury when compared to placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics Committee of Peking University First Hospital (China), 17 March 2010, Approval number: 2009L00819

Study design
Multicenter double-blind placebo-controlled randomized confirmatory phase III 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
Minor soft tissue injuries, such as ankle or knee joint sprains, muscle strains or contusions

Interventions
Patients were randomised to receive either
1. DHEP medicated plaster (Flector®, IBSA Institut Biochimique SA): twice daily (morning and evening, every 12 hours) for 7 days
2. Placebo plaster: twice daily (morning and evening, every 12 hours) for 7 days

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Diclofenac epolamine

Primary outcome measure
Reduction in pain on movement (VAS score) at the end of treatment (Day 7), as com-pared to pre-treatment scores

Secondary outcome measures
1. Pain on movement day-by-day evaluation (VAS score)
2. Summed pain intensity difference (SPID)
3. Rescue medication consumption (paracetamol)
4. Overall treatment efficacy as judged by patient and Investigator
5. Compliance to treatment
6. Overall treatment tolerability as judged by patient and Investigator

7. Adverse events
8. Pre-/post-treatment changes in haematology, blood chemistry, urinalysis or ECG tests

Overall study start date
01/04/2010

Completion date
30/11/2010

Eligibility

Key inclusion criteria
1. Outpatients and emergency patients of both gender
2. Aged between 18 and 65 years
3. With a minor soft tissue injury occurred within the past 72 hours
4. With pain on movement greater than or equal to 50 mm on VAS

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
384

Key exclusion criteria
1. Severe injuries requiring orthopaedic, surgical or physiotherapeutic treatment
2. Open skin lesion or any dermatological condition at treated site
3. Administration of any topical medication within the past 24 hours
4. Administration of OTC analgesic or NSAIDs within the past 36-48 hours
5. Administration of long-acting NSAIDs within the past 72 hours
6. Administration of narcotic analgesics within the past 7 days
7. Administration of systemic anti-inflammatory steroidal drugs within the past 60 days

Date of first enrolment
01/04/2010

Date of final enrolment
30/11/2010

Locations

Countries of recruitment

China

Study participating centre
Department of Orthopaedics
Beijing
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100034

Sponsor information

Organisation
Institut Biochimique SA (IBSA) (Switzerland)

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Sponsor type
Industry

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http://www.ibsa-international.com/

ROR
https://ror.org/051tj3a26

Funder(s)

Funder type
Industry

Funder Name
IBSA Institut Biochimique SA (Switzerland)

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