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Phase III trial of diclofenac sodium medicated plaster in patients with fresh injuries of the limbs

Submission date
24/01/2012

Recruitment status
No longer recruiting

Registration date
22/02/2012

Overall study status
Completed

Last Edited
01/08/2014

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
Fresh impact injuries are common injuries associated with sports activities and normal daily activities. These injuries are often recognized by the onset of immediate localized pain, swelling, discolouration and limited joint range of motion near the injury. They are characterized by direct trauma to the muscle group with subsequent pain and swelling resulting from bleeding within the muscle. The aim of this study is to assess whether a diclofenac medicated plaster reduces pain caused by fresh impact injuries of the limbs.

Who can participate?
Patients aged between 18 and 60 years with fresh impact injuries of the limbs (sprain, strain, contusion) not older than 3 hours.

What does the study involve?
Patients will be randomly allocated to be treated with either the diclofenac patch group or a placebo (dummy) patch. The treatment will be administered two times a day, in the morning and in the evening for 7 days.

What are the possible benefits and risks of participating?
If you receive the diclofenac plaster, it is possible that your pain may be reduced. If your pain gets worse you will be withdrawn from the study. Caution is required in patients with gastric and intestinal ulcers. For safety reasons these patients may not participate in the trial. Some skin reactions could be expected such as rash, itching, burning and reddening of the skin.

Where is the study run from?
The study takes place in four centres in Germany. Some of them are close to sport centres with several sport grounds. The coordinator site is headed by Prof. Hans Georg Predel.

When is the study starting and how long is it expected to run for?
The study started in September 2010 and ran until April 2011.

Who is funding the study?
Fidia Farmaceutici S.p.A. (Italy).

Who is the main contact?
Nicola Giordan
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Contact information

Type(s)
Scientific

Contact name
Prof Hans-Georg Predel

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Additional identifiers

Protocol serial number
Q16-10-01

Study information

Scientific Title
Randomised, double-blind, placebo-controlled, parallel-groups, multi-centre clinical trial phase III with diclofenac sodium 140 mg medicated plaster in patients with fresh impact injuries of the limbs

Study objectives
Assess the efficacy of diclofenac sodium 140 mg medicated plaster over placebo plaster as assessed by pain intensity difference in the indication fresh impact injuries of the limbs

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Rhine Ethics Committee [Ethik-Kommission der Ärztekammer Nordrhein], 28/08/2010, ref: 2010203

Primary study design
Interventional

Study design
Randomised double-blind placebo-controlled parallel groups multi-centre clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Impact injury of the limbs

Interventions
Treatment (diclofenac or placebo) is started after enrolment into the trial (at Visit 1, after obtaining informed consent and after physical examination and performance of all trial-specific measurements) and administered two times a day, in the morning and in the evening, and continued until Day 8, inclusive.

The visits were performed according to the following scheme:
Visit 1 - day 1 (baseline): enrollment and start of therapy
Visit 2 - day 2 (24 ±4 hours after baseline): during study treatment
Visit 3 - day 3 (48 ±4 hours after baseline): during study treatment
Visit 4 - day 5 (4 days after baseline): during study treatment
Visit 5 - day 8 (7 days after baseline): patient's final evaluation

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
Absolute change in pain on movement - assessed while moving the arm lifting a barbell (in case of injury of upper limb) or walking five steps on an even surface (in case of injury of lower limb)

Measured at baseline Visit 1 (Day 1) to Visit 3 (Day 3) assessed by patient on Visual Analogue Scale (VAS)

Key secondary outcome(s)
1. Pain at rest, assessed by patient on VAS on Visit 3, 4 and 5
2. Pain on active movement, assessed by patient on VAS on Visit 4 and 5
3. Algometric pain measurement directly on the skin at the injured site and the contralateral site on Visit 3 and Visit 4
4. Time to onset of efficacy assessed by patient on Visit 2, possibly on Visit 3, 4 and 5, too. If the patient feels that the medication is not yet working at Visit 2, the investigator will ask the patient after the onset of efficacy again at subsequent visits until Visit 5
5. Global assessment of treatment efficacy by patient and by investigator, according to a 5-point Likert scale (none, poor, fair, good, excellent) at Visit 2, 3, 4, 5
6. Consumption of rescue medication at each visit

Safety outcomes:
1. Global assessment of local tolerability by patient and by investigator according to a 4-point scale (poor, fair, good, excellent) at Visit 2, 3, 4, 5
2. Changes from baseline to Visit 5 in general physical examination

3. Changes from baseline to Visit 3 and 5 in vital signs
4. Recording of adverse events

Completion date
14/04/2011

Eligibility

Key inclusion criteria
1. Males or females
2. Age range 18-60 years
3. Outpatients
4. Good general health
5. Written informed consent
6. Fresh impact injury of the limbs presented within 3 hours after injury
7. The size of the visible traumatisation must be at least 25 cm2 and maximal 150 cm2 (in case of a muscle strain the area is assessed through palpation)
8. Pain assessment on movement by patient 40 mm at baseline
9. Visit 1 on a 100 mm Visual Analogue Scale (VAS)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Key exclusion criteria
1. History of blood coagulation disorders
2. History of asthma, chronic obstructive pulmonary disease (COPD), hay fever and swelling of nasal mucosa
3. Pregnancy or lactation period
4. Women with childbearing potential without effective contraceptive methods
5. Known allergy or hypersensitivity to: diclofenac, paracetamol, acetylsalicylic acid, salicylic acid, other nonsteroidal antiinflammatory drugs (NSAIDs) or cyclooxygenase 2-specific inhibitor (COXIB) or known intolerance (cutaneous or systemic) to any of the ingredients of the plaster, such as butylated methacrylate copolymer, copolymer acrylate vinyl acetate, PEG 12 stearate, sorbitan oleate
6. Current skin disorders/open wounds in the area to be treated

7. Gastric and intestinal ulcer
8. Gastrointestinal, cerebrovascular or other active bleedings
9. Evidence of liver, kidney or haematopoetic disorders
10. Patients affected by rheumatoid arthritis or gout
11. Known malignant diseases in the last 5 years
12. Pre-treatment of injury. Previous cooling (ice, cooling spray) is authorised prior to screening. It is also allowed to cool the injury during the screening period until randomisation with a moist cloth and water at room temperature (no ice, no cooling spay)
13. Any patient in the investigators' opinion not considered suitable for enrolment
14. Anticipated poor compliance by the patient
15. Use of non-steroidal anti-inflammatory drugs, analgesics (e.g. acetyl salicylic acid, with the exception of paracetamol) or psychotropic agents within 3 days before trial participation or oral corticosteroids within 2 weeks or intravenous corticosteroids within 4 weeks before trial participation
16. Use of glucosamine, chondroitine sulphate, diacerine, hyaluronic acids and bisposphonates in the last 4 weeks
17. Participation in another clinical trial and/or treatment with an experimental drug within 4 weeks before participation in the trial
18. Previous participation in this clinical trial
19. Any relevant surgical treatment during the previous 2 months or planned during the trial
20. Patient with a history of serious psychiatric disorders
21. Abuse of alcohol, medicaments or illicit drugs

Date of first enrolment
14/09/2010

Date of final enrolment
14/04/2011

Locations

Countries of recruitment
Germany

Study participating centre
Deutsche Sporthochschule Köln
Cologne
Germany
50933

Sponsor information

Organisation
Fidia Pharmaceutical [Fidia Farmaceutici S.p.A.] (Italy)

ROR

https://ror.org/00dy5wm60

Funder(s)

Funder type
Industry

Funder Name
Fidia Pharmaceutical [Fidia Farmaceutici S.p.A.] (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration