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

Submission date	Recruitment status	Prospectively registered
24/01/2012	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
22/02/2012	Completed	Results
Last Edited	Condition category	Individual participant data
01/08/2014	Injury, Occupational Diseases, Poisoning	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 If your pain gets worse you will be withdrawn from the study.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 ngiordan@fidiapharma.it

# **Contact information**

# Type(s)

Scientific

#### Contact name

Prof Hans-Georg Predel

#### Contact details

Deutsche Sporthochschule Köln Institut für Kreislaufforschung und Sportmedizin Am Sportpark Müngersdorf 6 Cologne Germany 50933

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

**Secondary identifying numbers** O16-10-01

# 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

# Study design

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

# 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

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 measure

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)

# Secondary outcome measures

- 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

# Overall study start date

14/09/2010

## 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

#### Age group

Adult

#### Lower age limit

18 Years

#### Upper age limit

60 Years

#### Sex

Both

# Target number of participants

160

## 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)

# Sponsor details

Via Ponte della fabbrica 3/A Abano Terme - Padova Italy 35031 ngiordan@fidiapharma.it

# Sponsor type

Industry

#### Website

http://www.fidiapharma.com

#### **ROR**

https://ror.org/00dy5wm60

# Funder(s)

# Funder type

Industry

# **Funder Name**

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

# **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