# Effect of treatment with L0006CP on the time of fracture-healing

Submission date 23/02/2011	<b>Recruitment status</b> No longer recruiting	Prospectively registered
		☐ Protocol
Registration date 07/04/2011	Overall study status Completed	Statistical analysis plan
		[X] Results
Last Edited	Condition category	Individual participant data
20/05/2019	Injury, Occupational Diseases, Poisoning	

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

#### Type(s)

Scientific

#### Contact name

Prof Stanislaw Pomianowskip

#### Contact details

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# Additional identifiers

# EudraCT/CTIS number

2010-020973-18

**IRAS** number

05-400

ClinicalTrials.gov number

# Secondary identifying numbers

2010-020973-18

# Study information

#### Scientific Title

Effect of treatment with L0006CP on the time of fracture-healing: a prospective, multi-centre, double-blind, randomised, placebo controlled clinical trial

#### Acronym

L0006CP

#### **Study objectives**

To compare the effect of a treatment with ossein L0006CP compound versus a placebo on the time of fracture-healing in patients with a wrist fracture

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration.

Bioethical committee of Centre for Medical Education, Warsaw (Centrum Medyczne Kształcenia) - approval pending

#### Study design

Prospective multicentre double-blind randomised placebo controlled 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

Wrist fracture

#### **Interventions**

L0006CP film-coated tablets OR placebo tablets for 12 weeks (1 tablet twice a day)

## Intervention Type

Other

#### Phase

#### Primary outcome measure

Comparison between the two treatments, of the time to radiological healing in the two groups

#### Secondary outcome measures

Comparison between the two groups of:

- 1. Time to disappearance of fracture line
- 2. Time to full normal activity of daily living involving the target upper limb
- 3. Percentage of patients with at least one adverse event occurring under treatment

#### Overall study start date

15/03/2011

#### Completion date

15/10/2011

# Eligibility

#### Key inclusion criteria

- 1. Male or menopausal female between 50 and 80 years of age
- 2. A recent closed Colles fracture, correctly reduced and stabilised
- 3. Willing, able to understand and sign an approved informed consent form
- 4. Able to understand the protocol and to come to the control visits

## Participant type(s)

Patient

#### Age group

Adult

#### Sex

Both

#### Target number of participants

90

## Total final enrolment

58

#### Key exclusion criteria

- 1. Fractures not meeting inclusion criteria (including pathological fractures)
- 2. Previous or concomitant treatment that may influence recovery
- 3. Concomittant treatments interfering with bone metabolism

#### Date of first enrolment

15/03/2011

#### Date of final enrolment

15/10/2011

# Locations

#### Countries of recruitment

Poland

## Study participating centre

Klinika Chirurgii Urazowej Narządu Ruchu i Ortopedii CMKP Samodzielny Publiczny Szpital Kliniczny

Otwock

Poland

05-400

# Sponsor information

# Organisation

Pierre Fabre (France)

## Sponsor details

Canceropole 3 Avenue Hubert Curien BP13562 Toulouse Cedex France 31035

#### Sponsor type

Industry

#### **ROR**

https://ror.org/04hdhz511

# Funder(s)

#### Funder type

Industry

#### **Funder Name**

Pierre Fabre (France)

# **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

**Study outputs** 

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Basic results20/05/2019NoNo