

Effect of treatment with L006CP on the time of fracture-healing

Submission date
23/02/2011

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
07/04/2011

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
20/05/2019

Condition category
Injury, Occupational Diseases, Poisoning

Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2010-020973-18

Protocol serial number
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

Study type(s)

Treatment

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

Not Applicable

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/04hdhz511>

Funder(s)

Funder type

Industry

Funder Name

Pierre Fabre (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			20/05/2019	No	No