ISRCTN71678602 https://doi.org/10.1186/ISRCTN71678602

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

Submission date	Recruitment status
23/02/2011	No longer recruiting
Registration date	**Overall study status**
07/04/2011	Completed
Last Edited	**Condition category**
20/05/2019	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2010-020973-18

IRAS number

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

Not Applicable

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