Second study on the Effect of Teriparatide on Femoral Neck Fracture Healing

Published: 14-03-2012
Last updated: 01-05-2024

Improvement of the functional recovery of patients with a hipfracture and the prevention of re-surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON39475

Source
ToetsingOnline

Brief title
GHDQ

Condition

- Fractures

Synonym
hip fracture, surgical intervention

Research involving
Human

Sponsors and support

Primary sponsor: Eli Lilly
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: fracture, healing, hip, surgery

Outcome measures

Primary outcome

men and postmenopausal women >=50 years of age with successful fracture healing

12 months after a hip fracture.

Secondary outcome

Patient Questionnaires outcome

Study description

Background summary

Currently, hip fractures occur in approximately 300,000 patients/year in the United States (US) and 600,000 patients/year in Europe. A fair number of all hip fractures involve the femoral neck. There is an increasing rise in the hip fracture rate with increasing age and, in the elderly, most hip fractures occur after low-trauma injury such as a fall from standing height or less.

During hip-fracture recovery, most patients have pain at the fracture site, decreased mobility, and reduced ability to perform activities of daily living. The loss of mobility and function can be prolonged with up to 50% of patients failing to regain their prehip fracture functional level.

Study objective

Improvement of the functional recovery of patients with a hipfracture and the prevention of re-surgery.

Study design

Second Study of the Effect of Teriparatide on Femoral Neck Fracture Healing

Intervention

teriparatide 20 microgram per day via subcutaneous injection versus placebo

Study burden and risks

4 questionaires need to be filled out several times, a walking test needs to be done several times using utilities such as a cane or walker; which is decribed in detail in the patient information.
x-ray burden, venapuntions, subcutane injections

Contacts

Public
Eli Lilly

Grootslag 1 - 5
Houten 3991 RA
NL
Scientific
Eli Lilly

Grootslag 1 - 5
Houten 3991 RA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Community dwelling men and postmenopausal women aged >=50 years who were ambulatory before sustaining a low-trauma, unilateral femoral neck fracture (displaced or non-displaced) ;Other than femoral neck fracture, be free of incapacitating conditions and

have a life expectancy of at least 2 years;Have received or are eligible for treatment with internal fixation (sliding hip screw or multiple cancellous screws) for the femoral neck fracture (the surgical procedure itself is not a part of this protocol);Have given written informed consent (patient or proxy) after being informed of the risks, medications and study procedures

Exclusion criteria

Increased baseline risk of osteosarcoma;History of unresolved skeletal diseases affecting bone metabolism other than primary osteoporosis and any secondary causes of osteoporosis ;Abnormally elevated values of serum calcium at baseline ;Abnormally elevated values of serum intact parathyroid hormone (PTH) (1-84) at baseline ;Severe vitamin D deficiency at baseline defined as 25-hydroxy-vitamin D levels <9.2 ng/mL;Active liver disease or jaundice;Significantly impaired renal function at baseline ;Abnormal thyroid function not corrected by therapy;History of a malignant neoplasm in the 5 years prior to Visit 1, with the exception of superficial basal cell carcinoma or squamous cell carcinoma of the skin that has been definitively treated.;History of bone marrow or solid-organ transplantation;History of symptomatic nephrolithiasis or urolithiasis in 1 year prior to visit;Prior treatment with PTH, teriparatide or other PTH analogs;Local or systemic treatment with bone morphogenic proteins or any growth factor;Previous fracture or bone surgery in the currently fractured hip;Treatment with bone grafting or osteotomies;Soft tissue infection at the operation site;Treatment with augmentation using any type of degradable cement, hydroxyapatite-coated implants or with non-invasive interventations;Associated major injuries of a lower exteremity including fractures of teh foot, ankle, tibia, fibula, knee, femur, femoral head, or pelvis; dislocations of the ankle, knee, or hip.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2011
Enrollment:	4
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Forsteo
Generic name:	teriparatide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	14-03-2012
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	20-03-2012
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	15-05-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	21-05-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	20-06-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Approved WMO Date:	21-06-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	20-12-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	07-01-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	28-01-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	29-01-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	16-05-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2011-001116-65-NL
CCMO	NL38359.075.11