

EXFOS - A European prospective observational study to evaluate fracture outcomes, back pain, health-related quality of life, and compliance in patients with osteoporosis during and after treatment with Forsteo®

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Last update : 08/01/2012 | Version : 2 | ID : 79

General

Identification

Detailed name A European prospective observational study to evaluate fracture outcomes, back pain, health-related quality of life, and compliance in patients with osteoporosis during and after treatment with Forsteo®

Sign or acronym EXFOS

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL N°910339

General Aspects

Medical area Rheumatology

Keywords Osteoporotic patients, teriparatide, duration of treatment, conditions of use

Scientific investigator(s) (Contact)

Name of the director Médecin pharmacoépidémiologiste

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Unit Eli Lilly France

Collaborations

Funding

Funding status Private

Details Eli Lilly and Company

Governance of the database

Sponsor(s) or organisation(s) responsible Eli Lilly

Organisation status Private

Additional contact

Main features

Type of database

Type of database Study databases

Study databases (details) Longitudinal study (except cohorts)

Database recruitment is carried out by an intermediary A selection of health care professionals

Database recruitment is made on the basis of: Medication(s) taken

Database recruitment is carried out as part of an interventional study No

Additional information regarding sample selection. France: recruitment by rheumatologists in the course of routine care. Random selection of rheumatologists using professional listing.

Database objective

Main objective Primary objective: determine the incidence of clinical vertebral fractures and non-vertebral fragility fractures in patients treated with teriparatide for about 18 months and a post-treatment follow-up period of at least 18 months. Secondary objectives: observance, treatment switching and cessation, clinical evolution, occurrence of back pain, direct costs linked to fractures.

Inclusion criteria Osteoporotic patients initiating treatment with teriparatide according to the practitioner's opinion in routine care

Population type

Age Adulthood (19 to 24 years)
Adulthood (25 to 44 years)
Adulthood (45 to 64 years)
Elderly (65 to 79 years)
Great age (80 years and more)

Population covered	Sick population
Gender	Male Woman
Geography area	International
Detail of the geography area	Croatia, Denmark, France, Greece, Italy, Norway, Slovenia and Sweden
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2006
Date of last collection (YYYY or MM/YYYY)	2012
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	1607
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services Quality of life/health perception
Care consumption (detail)	Medicines consumption
Procedures	
Data collection method	Study data collection form

Participant monitoring	Yes
Details on monitoring of participants	36 months maximum

Links to administrative sources	No
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Promotion and access

Promotion

Link to the document	http://tinyurl.com/Pubmed-EXFOS
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Description	List of publications in Pubmed
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Access

Terms of data access (charter for data provision, format of data, availability delay)	Report and publication
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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