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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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
Email	Fr_mail_pharmacoepi@lilly.com
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 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

Promotion and access

Promotion

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

Access

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