

# 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

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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
<b>Additional contact</b>	
<b>Main features</b>	
<b>Type of database</b>	
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.
<b>Database objective</b>	
Main objective	<p>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.</p> <p>Secondary objectives: observance, treatment switching and cessation, clinical evolution, occurrence of back pain, direct costs linked to fractures.</p>
Inclusion criteria	Osteoporotic patients initiating treatment with teriparatide according to the practitioner's opinion in routine care
<b>Population type</b>	
Age	<p>Adulthood (19 to 24 years)</p> <p>Adulthood (25 to 44 years)</p> <p>Adulthood (45 to 64 years)</p> <p>Elderly (65 to 79 years)</p> <p>Great age (80 years and more)</p>

Population covered	Sick population
Gender	Male Woman
Geography area	International
Detail of the geography area	Croatia, Denmark, France, Greece, Italy, Norway, Slovenia and Sweden
<b>Data collection</b>	
<b>Dates</b>	
Date of first collection (YYYY or MM/YYYY)	2006
Date of last collection (YYYY or MM/YYYY)	2012
<b>Size of the database</b>	
Size of the database (number of individuals)	[500-1000[ individuals
Details of the number of individuals	1607
<b>Data</b>	
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
<b>Procedures</b>	
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	<a href="http://tinyurl.com/Pubmed-EXFOS">http://tinyurl.com/Pubmed-EXFOS</a>
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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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