PRESAGE - Observationnal study on Postmenopausal woman

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General

Identification

Detailed name	Observationnal study on Postmenopausal woman
Sign or acronym	PRESAGE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL N°907026

General Aspects

Medical area	Rheumatology
Others (details)	osteoporosis
Keywords	Postmenopausal women, mineral bone density, osteoporosis

Scientific investigator(s) (Contact)

Name of the director	Hébuterne
Surname	Xavier
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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)	Not-repeated cross-sectional studies (except case control studies)
Database recruitment is carried out by an intermediary	A selection of health care professionals A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Recruitment of patients in private-practicing or hospital BMD centers directed by rheumatologists in the normal practice of care.

Database objective

Main objective	Primary objective: estimate the percentage of osteoporotic patients among postmenopausal patients with a mineral bone density measurement for diagnosis purposes and who can benefit from therapeutic recommendations according to French recommendations. Secondary objectives: factors associated with osteoporosis, characteristics and care for patients
Inclusion criteria	Postmenopausal woman, - Patient not treated for osteoporosis for at least one year (HRT, raloxifene, bisphosphonate, teriparatide, strontium ranelate), - Patient coming for a bone densitometry for diagnosis purposes, - Patient able to benefit from a therapeutic recommendation for the treatment of osteoporosis (osteopenic or osteoporotic patient with risk factors of fractures).

Population type

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

Population covered	Sick population
Gender	Woman
Geography area	National
Detail of the geography area	National

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2007
Date of last collection (YYYY or MM/YYYY)	2008

Size of the database

Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	646

Data

Database activity	Data collection completed
Type of data collected	Clinical data Paraclinical data
Clinical data (detail)	Direct physical measures Medical registration
Paraclinical data (detail)	Bone densitometry
Presence of a biobank	No
Health parameters studied	Health event/morbidity

Procedures

Data collection method	Data collection notebook
Participant monitoring	No
Links to administrative sources	No

Promotion and access

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