

ORBIT - Comorbidities associated with peripheral neuropathic pain (PNP)

Head :Millet Véronique, Pfizer

Last update : 01/01/2018 | Version : 1 | ID : 111

General	
Identification	
Detailed name	Comorbidities associated with peripheral neuropathic pain (PNP)
Sign or acronym	ORBIT
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL N° 906289
General Aspects	
Medical area	Neurology
Others (details)	Peripheral neuropathic pain (PNP)
Scientific investigator(s) (Contact)	
Name of the director	Millet
Surname	Véronique
Address	23-25 avenue du Dr Lannelongue, 75668 paris cedex 14
Phone	+33 (0)1 58 07 34 12
Email	veronique.millet@pfizer.com
Unit	Pfizer
Collaborations	
Funding	
Funding status	Private
Details	Pfizer

Governance of the database	
Sponsor(s) or organisation(s) responsible	Pfizer
Organisation status	Both
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 institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Recruitment through participating doctors
Database objective	
Main objective	Primary: - Evaluate the frequency of anxiety and mood disturbances and the degree of sleeping disorders in patients monitored for PNP Secondary: - Describe the links between the components of the PNP and the existence of anxiety, mood disturbances and the degree of sleeping disorders, - Describe the relations between the components of PNP, anxiety, sleeping disorders, mood disturbances on the one hand and the quality of life on the other hand, - Describe the relation between the components of the PNP, the existence of anxiety and mood disturbances, the degree of sleep disorders on the one hand and the current drug care of patients on the other hand.
Inclusion criteria	Patients > 18 years, - Peripheral neuropathic pain (in relation with a lesion of the peripheral nervous system). - Intensity of the pain > 3 on the NVS, - Radiculalgia without lumbar pain or with lumbar

pain of which the intensity of the pain is < 3 on the NVS (intensity of the lumbar pain from 0 to 2),
 - Through general neurology: patient consulting for his PNP or for the etiology of this PNP,
 - Through home consultation: patient consulting for a PNP for the 1st or 2nd consultation.

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	National
----------------	----------

Detail of the geography area	Metropolitan France
------------------------------	---------------------

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2006
--	------

Date of last collection (YYYY or MM/YYYY)	2008
---	------

Size of the database

Size of the database (number of individuals)	< 500 individuals
--	-------------------

Details of the number of individuals	195
--------------------------------------	-----

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)	Face to face interview
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services
Care consumption (detail)	Medical/paramedical consultation
Procedures	
Data collection method	Paper CRF
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)	methods for accessing the database are currently being defined
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only