

ZEN - An observational study of olanzapine coated and orodispersible tablets effectiveness in schizophrenic and bipolar outpatients

Head :Médecin pharmacoépidémiologiste , Eli Lilly France

Last update : 01/01/2019 | Version : 2 | ID : 72

General

Identification

Detailed name	An observational study of olanzapine coated and orodispersible tablets effectiveness in schizophrenic and bipolar outpatients
Sign or acronym	ZEN
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL N°907035

General Aspects

Medical area	Neurology Psychology and psychiatry
Keywords	bipolar disorders, olanzapine and duration of treatment, Schizophrenia

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)	Eli Lilly
-------------------------------	-----------

responsible

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: random selection of psychiatrists using a national professional file. Recruitment consecutive to patients followed in ambulatory mode (external consultation or liberal practice)

Database objective

Main objective

The primary objective of this study is to assess the proportion of schizophrenic patients and the proportion of bipolar patients who discontinued olanzapine within 12 months of treatment in outpatient, ambulatory or community settings.

Inclusion criteria

Patients aged 18 years and older,
- suffering from bipolar disorders or schizophrenic disorders according to DSM-IV criteria,
- initiating or having initiated a treatment via olanzapine in tablet or orodispersible form.

Population type

Age

Adulthood (19 to 24 years)
Adulthood (25 to 44 years)
Adulthood (45 to 64 years)

Population covered

Sick population

Gender

Male
Woman

Geography area	International
Detail of the geography area	France, Deutschland and Greece
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2007
Date of last collection (YYYY or MM/YYYY)	2009
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	927
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 Quality of life/health perception Others
Other (detail)	Alliance and therapeutic observance
Procedures	
Data collection method	Data collection notebook and questionnaires
Participant monitoring	Yes
Details on monitoring of participants	1 year follow up

Links to administrative sources	No
---------------------------------	----

Promotion and access

Promotion

Link to the document	http://tinyurl.com/Pubmed-Etude-ZEN
----------------------	---------------------------------------------------------------------------------------

Description	List of publications in Pubmed
-------------	--------------------------------

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
---------------------------	---------------------------------