

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

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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_pharmacoepepi@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