

# 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<br>Psychology and psychiatry  |
| Keywords   | bipolar disorders, olanzapine and duration of treatment, Schizophrenia  |
| Scientific investigator(s)<br>(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   | <p>Patients aged 18 years and older,</p> <ul style="list-style-type: none"> <li>- suffering from bipolar disorders or schizophrenic disorders according to DSM-IV criteria,</li> <li>- initiating or having initiated a treatment via olanzapine in tablet or orodispersible form.</li> </ul> |
| Population type  |   |
| Age  | <p>Adulthood (19 to 24 years)</p> <p>Adulthood (25 to 44 years)</p> <p>Adulthood (45 to 64 years)</p>   |
| Population covered   | Sick population   |
| Gender   | <p>Male</p> <p>Woman</p>  |

|  |   |
|--|---|
| 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<br>Declarative data                                     |
| Clinical data (detail)                       | Direct physical measures<br>Medical registration                      |
| Declarative data (detail)                    | Paper self-questionnaire  |
| Presence of a biobank                        | No  |
| Health parameters studied                    | Health event/morbidity<br>Quality of life/health perception<br>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  | <a href="http://tinyurl.com/Pubmed-Etude-ZEN">http://tinyurl.com/Pubmed-Etude-ZEN</a> |
| 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   |