Post-injection Syndrome in Patients with Schizophrenia Receiving Olanzapine Long-Acting Injection (F1D-MC-B034)

First published: 29/02/2016

Last updated: 30/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS12592

Study ID

20541

DARWIN EU® study

No

Study countries

- ☐ Australia
- ☐ Austria
- ☐ Belgium
- ☐ Bulgaria

- [ ] Croatia
- [ ] Czechia
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Ireland
- [ ] Israel
- [ ] Italy
- [ ] Lithuania
- [ ] New Zealand
- [ ] Poland
- [ ] Romania
- [ ] Slovakia
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

This is a noninterventional, multi-country prospective study designed to assess the incidence of Post-Injection Syndrome events in patients treated with olanzapine long-acting injection (LAI). For the study, post-injection syndrome is defined as an event reported in temporal association with an injection of olanzapine LAI that presents with signs and symptoms consistent with olanzapine overdose. The investigator will record on the data capture form all adverse events (AEs) that occur within 24 hours following an injection and will provide a clinical opinion as to whether the patient has experienced a potential

post-injection syndrome event. An adjudication committee will review all cases. The study will characterize the clinical presentation and outcomes of post-injection syndrome, as well as to seek to identify potential risk factors associated with their occurrence. Approximately 5 000 patients will enter this multi-center study to achieve 92 500 injections.

Study status

Finalised

Research institutions and networks

Institutions

Eli Lilly and Company

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Meyers Kristin meyers_kristin_joy@lilly.com

Study contact

meyers_kristin_joy@lilly.com

Primary lead investigator

Meyers Kristin

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 06/08/2008

Study start date
Actual: 07/04/2009

Date of final study report
Planned: 30/06/2016

Actual: 29/06/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

B034_protocol_amendment_c_22May2014_OSP(c).pdf (3.28 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The primary objective is to estimate the incidence per injection and per patient of post-injection syndrome events in schizophrenia patients receiving olanzapine long-acting injection.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N05AH03) olanzapine

olanzapine

Medical condition to be studied

Schizophrenia

Population studied

Short description of the study population

Adult patients with schizophrenia whose physician has decided to treat with olanzapine LAI.

Male or female patients, at least 18 years of age who have been diagnosed with schizophrenia and willing to participate in the study and have signed a consent form to release medical information were included.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Patients with schizophrenia

Estimated number of subjects

5000

Study design details

Outcomes

Post-injection syndrome, - Clinical presentation and outcomes of post-injection syndrome- Potential risk factors association with post-injection syndrome- Hospitalization at baseline and post-baseline

Data analysis plan

For primary analysis, the crude incidence of post-injection syndrome events and 95% confidence intervals will be calculated based on the total number of patients enrolled in the study and the total number of injections given in the study period. Post-injection syndrome events used in the incidence will be based on adjudicated cases. Secondary analyses will include descriptive statistics of the study population and characterize the clinical presentation of post-injection syndrome events, including outcome. Adjusted odds ratios and 95% confidence intervals will be calculated using logistic regression to identify risk factors for patients experiencing post-injection syndrome events. Hospitalization at baseline (previous 6- or 12-months) and post-baseline will be tabulated for all enrolled patients. Descriptive statistics will be used to describe the frequency and duration of hospitalization.Additional analyses include the summarization of adverse events and serious adverse events.

Documents

Study results

B034 Non-Interventional PASS Report redacted.pdf (1.47 MB)

Study publications

Bushe CJ, Falk D, Anand E, Casillas M, Perrin E, Chhabra-Khanna R, Detke HC. Ol…

Jones ME, Andrews JS, Faries DE, Landry J, Xu J, Detke HC, Chhabra-Khanna R, Mc…

Meyers KJ, Upadhyaya HP, Landry JL, Chhabra-Khanna R, Falk DM, Rao BS, Jones ME…

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No