

# 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](mailto:meyers_kristin_joy@lilly.com)

### Primary lead investigator

Meyers Kristin

## 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