

**Unique Protocol ID:** 11684

**Brief Title:** A Study of Patients With Schizophrenia and Events That Occur After an Injection of Olanzapine Long-acting Injection

**Official Title:** Post-Injection Syndrome in Patients With Schizophrenia Receiving Olanzapine Long-Acting Injection

**Secondary IDs:** F1D-MC-B034

**Study Type:** Observational

**Sponsor:** Eli Lilly and Company

**Collaborator(s):** N/A

**Brief Summary:** This study is a noninterventional prospective study designed to assess the incidence of Post-Injection Syndrome events in patients treated with olanzapine Long-Acting Injection (olanzapine LAI) This study is planned to be conducted in multiple countries where olanzapine LAI is marketed. A Post-Injection Syndrome event 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 (post injection).

**Detailed Description:** This observational trial is designed to estimate the incidence of Post-Injection Syndrome events in "real-world" clinical practice as well as better characterize the clinical presentation and outcomes. This study will also seek to identify potential risk factors associated with Post-Injection Syndrome events.

**Overall Status:** Enrolling by Invitation

**Study Start Date:** April 2009

**Study Completion Date:** March 2013 Anticipated

**Study Design:**

Observational Study Model: Cohort

Time Perspective: Prospective

Biospecimen Retention: None Retained

Biospecimen Description: N/A

Enrollment: 2750 (anticipated)

**Primary Outcome Measure:**

Measure: Incidence of Post-Injection syndrome events. 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 number of injections given in the study period.

Timeframe: baseline to end of study (92, 500 injections)

**Secondary Outcome Measures:**

Measure: Characterize the type of Post-Injection syndrome by clinical presentation and outcome. Descriptive statistics will be used to describe the study population and characterize the clinical presentation of Post-Injection Syndrome events including outcome

Timeframe: baseline to end of study (92, 500 injections)

Measure: Change from baseline in number of hospitalizations. Hospitalization at baseline and postbaseline will be tabulated for all enrolled patients. Descriptive statistics will be used to describe the frequency and duration of hospitalization

Timeframe: baseline to end of study (92, 500 injections)

Measure: Identify potential risk factors of Post-Injection syndrome. Adjusted odds ratios and 95% confidence intervals will be calculated using logistic regression to identify risk factors for patients experiencing Post-Injection syndrome events

Timeframe: baseline to end of study (92, 500 injections)

**Conditions or Focus of Study:** Schizophrenia

Groups/Cohorts	Interventions
olanzapine long acting injection  patients receiving commercially-available olanzapine LAI in accordance with their physician's standard of care	Drug: olanzapine long acting injection  Intramuscular gluteal injection administered every 2 or 4 weeks in 210, 300 or 405mg reconstituted to a fixed concentration of 150mg/ml

**Sample Population Description:** Eligible patients will include adult patients with schizophrenia whose physician has decided to treat with olanzapine long acting injection.

**Sampling Method:** Non-Probability Sample

**Eligibility Criteria:**

**Inclusion Criteria:**

- Patients can be male or female, at least 18 years of age who have been diagnosed with schizophrenia.
- Patient must be willing to participate in the study.
- Patients must sign a consent to release medical information form.

**Exclusion Criteria:**

- Patients cannot be investigator site personnel directly affiliated with the study and/or their immediate family. Immediate family is defined as a spouse, parent, child or sibling whether biological or legally adopted.
- Patients cannot participate if they will not or cannot sign a consent to release medical information form.

**Gender:** Both

**Minimum Age:** 18 years

**Maximum Age:** N/A

**Contact for public queries:** This study is enrolling by invitation

**Contact for scientific queries:** Call 1-877-CTLILLY (1-877-285-4559) or 1-317-615-4559  
Mon - Fri 9 AM - 5 PM Eastern time (UTC/GMT - 5 hours, EST)