A cohort study to investigate the risk of severe hypoglycemia among diabetic patients treated with Lyumjev® using the Medical Data Vision (MDV) database in Japan (I8B-JE-B003)

First published: 17/04/2023

Last updated: 23/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS104508

Study ID

104509

DARWIN EU® study

No

Study countries

☐ Japan

Study description

Primary Objective To describe the incidence proportion and incidence rate of first severe hypoglycemia requiring any hospital visit among adult patients (≥18-years-old) with diabetes treated with Lyumjev under routine care, and among the following subgroups: patients using (continuous subcutaneous insulin infusion (CSII), patients treated using combination therapy with long-acting insulin analog therapy, patients with a diagnosis of type 1 diabetes, and patients with a diagnosis of type 2 diabetes.

Study status

Planned

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

Machiko Minatoya jpmail_encepp@lilly.com

Study contact

jpmail_encepp@lilly.com

Primary lead investigator

Machiko Minatoya

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 12/04/2023

Study start date
Planned: 01/12/2019

Date of final study report
Planned: 29/02/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly Japan K.K.

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The primary objective is to describe the incidence proportion and incidence rate of first severe hypoglycemia requiring any hospital visit among: • Adult patients (?18-years-old) with diabetes treated with Lyumjev under routine care

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

LYUMJEV

Medical condition to be studied

Hypoglycaemia

Population studied

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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)

Estimated number of subjects

5190

Study design details

Outcomes

severe hypoglycemia

Data analysis plan

Incidence proportion of first severe hypoglycemia (n/N, %) will be calculated.

Incidence rate and its 95% CI of the first severe hypoglycemia requiring any

hospital visit among the Lyumjev treated cohort will be calculated as the number events per 100 person-years.

Data management

Data sources

Data source(s), other

MDV Japan

Data sources (types)

Administrative healthcare records (e.g., claims)

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