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

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Study contact

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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

Medicinal product name

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

5.190

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

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 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