Risk Factors Associated with Severe Hypoglycemia Among Patients with Type 2 Diabetes Mellitus Treated with Insulin (Risk factors for severe hypoglycemia)

First published: 05/11/2019

Last updated: 22/02/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS31111

Study ID

39784

DARWIN EU® study

No

Study countries

United States

Study description

Diabetes mellitus is one of the most common chronic health conditions in the world. While type 2 diabetes mellitus (T2DM) can initially be managed with noninsulin therapies, insulin therapy is typically required to achieve glycemic control after disease progression. Progression of T2DM and insulin therapy can lead to a higher risk of hypoglycemia. Although hypoglycemia has been accepted by patients and providers as an inevitable consequence of preventing long-term diabetes complications, recent studies have found that hypoglycemia, including the severe form, is a potentially preventable cause of morbidity, mortality, high costs and impaired quality of life. Identification of additional risk factors will help clinicians recognize that there are factors which can lead to severe hypoglycemia and that it is essential that patients be prepared for hypoglycemia and severe hypoglycemia at all times if they are taking insulin.Primary and secondary study objectives:1. To identify risk factors for severe hypoglycemic (SH) events in insulin-treated T2DM patients. Identification of patients at different risk of SH will be based on an evaluation of risk factors of SH using a retrospective nested case-control design. 2. To describe and compare baseline demographic and clinical characteristics in the following patient subgroups:• Patients who experience at least a SH event during the index period• Patients who have not experienced a SH event3. To describe and compare healthcare resource utilization (HCRU) and cost in T2DM patients on insulin in the patient subgroups described above.Research DesignThe study is a nested case control study using incidence density sampling based on retrospective administrative claims data in U.S. The primary aim is to test potential risk factors for severe hypoglycemia in addition to well-known risk factors identified from the literature and clinical insights.

Study status

Ongoing

Research institutions and networks

Institutions

IQVIA

United Kingdom

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Institution **Non-Pharmaceutical company** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ron Wade

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/10/2018

Study start date

Planned: 01/11/2019

Actual: 30/10/2019

Date of final study report
Planned: 30/06/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

2018-7840_T2DM SH_Non_interventional PASS Protocol_approved 30OCT2019 redacted.pdf (865.44 KB)

2018-7840_V4.0_T2DMSH_2_Approved 1FEB2021_dedacted.pdf (585.27 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

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:

To identify risk factors for severe hypoglycemic (SH) events in insulin-treated T2DM patients.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Medical condition to be studied

Insulin-requiring type 2 diabetes mellitus

Hypoglycaemia

Population studied

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)

Estimated number of subjects

10.000

Study design details

Outcomes

Severe hypoglycemia

Data analysis plan

For the primary and secondary objectives, a retrospective nested case-control study with incidence density sampling utilizing adjudicated healthcare administrative claims data will be used to identify risk factors of SH based on demographic and clinical characteristics in insulin-treated T2DM patients. Descriptive statistics will be reported using frequency and percentage distributions for categorical variables. Mean, median, and standard deviation will be generated as measures of central tendency and variance for continuous and count variables. Conditional logistic regression will be used to identify potential risk factors for SH after matching. Forward or backward variable selection procedures may be used to determine which variables to include in the final model.

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

IMS LifeLink: PharMetrics Plus - US

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