Dulaglutide Modified-Prescription-Event Monitoring Study and network database study: a multi-database collaborative research program of observational studies to monitor the utilisation and safety of dulaglutide in the EU

First published: 29/07/2016

Last updated: 19/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS14445

Study ID

44227

DARWIN EU® study

No

Study countries

- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] United Kingdom

Study description

Dulaglutide is a glucagon-like peptide-1 receptor agonist (GLP-1 RA) indicated for the treatment of patients with type 2 diabetes mellitus (T2DM). This targeted surveillance study will be conducted in order to monitor the occurrence of certain medical conditions in patients using dulaglutide in the EU. The study will quantify the occurrence and describe the characteristics of these conditions during the first 12 months after starting dulaglutide. The conditions being monitored include acute pancreatitis, hypersensitivity, pancreatic and thyroid cancers, cardiac conduction abnormalities, gastrointestinal effects, and medication errors. Additionally, for subpopulations receiving dulaglutide where safety data are usually classified as “missing information,” the distribution of these medical conditions will be described to determine if there are any differences compared to what is known for the target population. In order to assess the safety profile and utilisation of dulaglutide in the EU, a multi-database post-authorisation safety study (PASS) program will be administered by the DSRU. The DSRU will conduct a Modified Prescription-Event Monitoring (M-PEM) study in England, and it will coordinate a multi-country collaborative research program to address common aims and objectives, using existing data from three European electronic health record (EHR) databases. Each country will independently conduct an observational study developed in accordance with aims and objectives from an agreed base protocol.

Study status

Finalised

Research institutions and networks

Institutions

Drug Safety Research Unit (DSRU)

United Kingdom

First published: 10/11/2021

Last updated: 16/02/2024

Institution | Not-for-profit | ENCePP partner

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

First published: 29/03/2010

Last updated: 26/02/2024

Institution | Not-for-profit | ENCePP partner

Department of Biomedical and Dental Sciences and Morphofunctional Imaging, University of Messina

Italy

First published: 29/11/2021

Last updated: 20/08/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

First published: 07/01/2022

Last updated: 24/07/2024

Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Saad Shakir

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/12/2015

Actual: 14/12/2015

Study start date
Planned: 01/01/2015

Actual: 01/01/2015

Date of interim report, if expected
Planned: 01/08/2017

Actual: 28/02/2018

Date of final study report
Planned: 31/03/2020

Actual: 19/04/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly

Study protocol

Dulaglutide MPEM and network study protocol abstract for EUPAS Register.pdf
(111.34 KB)

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:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The overall aim of this multi-database PASS program is to assess and understand the utilisation and safety profile of dulaglutide in patients with Type II diabetes mellitus.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prescription event monitoring

Study drug and medical condition

Name of medicine

TRULICITY

Medical condition to be studied

Pancreatitis

Hypersensitivity

Thyroid cancer

Pancreatic carcinoma

Arrhythmia supraventricular

Conduction disorder

Gastrointestinal disorder

Medication error

Population studied

Short description of the study population

The study population will consist of new user patients with T2DM who were prescribed dulaglutide in the EU.

Age groups

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)

Special population of interest

Hepatic impaired

Other

Pregnant women

Renal impaired

Special population of interest, other

Patients with Pancreatitis, Hypersensitivity, Thyroid cancer, Pancreatic carcinoma, Arrhythmia supraventricular, Conduction disorder, Gastrointestinal disorder, Medication error

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Estimated number of subjects

10000

Study design details

Outcomes

To estimate the cumulative incidence in the first 12 months of treatment with dulaglutide of the following events of interest: (a) Acute pancreatitis (b) Hypersensitivity (c) Cardiovascular (CV) events and conduction abnormalities

(d) Gastrointestinal (GI) effects (e) Medication errors, For patients receiving dulaglutide: 1. To describe the baseline profile of patients 2. To explore time to onset of primary outcomes of interest and to explore predictors of risk 3. To describe the safety profile in sub-populations missing from the EU Risk Management Plan 4. To estimate the period prevalence of pancreatic and/or thyroid cancer

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Data analysis plan

To estimate the cumulative incidence of primary events of interest in the first 12 months after starting treatment: Crude annualised cumulative incidence (percent of total valid cohort exposed) and cumulative rate (according to 1000 patients exposed), with 95% binomial and poisson exact Confidence Intervals (CI) for events of interest will be calculated, respectively. Graphs of cumulative counts of events of interest, by month over the study period, will be examined for possible change in reporting over calendar time. Points that will be taken into account in the analysis are the baseline characteristics, possible confounding factors and background incidence of the selected events in the study population during the observation period regardless of duration of exposure to dulaglutide. The incidence rate of these events will also be explored by estimating hazard over time.

Documents

Study results

Dulaglutide MPEM and network study final report abstract for EUPAS Register.pdf(113.3 KB)

Data management

Data sources

Data source(s)

PHARMO Data Network

German Pharmacoepidemiological Research Database

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prescription event monitoring

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