Utilisation of dulaglutide in European countries: A cross-sectional, multi-country and multi-source drug utilisation study using electronic health record databases (H9X-MC-B010)

First published: 14/06/2016

Last updated: 02/11/2020

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/37875

EU PAS number

EUPAS13783

Study ID

37875

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

This study describes the frequency of dulaglutide use in different groups of patients in European countries, including the characterization of use by demographics, main comorbidities and comedications, overall and in subgroups of interest, including patients with specific diseases, children and adolescents, the elderly, and pregnant and breastfeeding women. Additionally, medication errors and off-label use will be described among patients using dulaglutide.

Study status

Finalised

Research institutions and networks

Institutions

Real World Evidence Solutions, IMS Health

- [ ] France

First published: 06/09/2011

Last updated: 20/08/2024

Institution | Other

Contact details

Study institution contact

Ayad Ali

Study contact

ali_ayad@lilly.com

Primary lead investigator

Ayad Ali

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/12/2014

Actual: 15/12/2014

Study start date

Planned: 13/06/2016

Actual: 13/06/2016

Date of final study report

Planned: 16/12/2019

Actual: 14/11/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

H9X-MC-B010_EU-PAS-Registered.pdf(1.48 MB)

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To describe the frequency of dulaglutide use in overall patients, and in subgroups of interest, including patients with severe renal failure, hepatic disease, heart failure, severe gastrointestinal disease, children and adolescents, elderly patients (75+ years), and pregnant and breastfeeding women. Additionally, to describe utilization in patients with medication errors and off-label use.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

The study population included all patients receiving dulaglutide prescriptions in the outpatient setting in the selected databases of five European target countries (i.e. France, Germany, Spain, Sweden, and the UK). The eligible patients were those for whom treatment with dulaglutide was initiated during the observation period in each wave of the study for patients having at least 6 months of available continuous history prior to the date of the first dulaglutide prescription (i.e. baseline period). There were no exclusion criteria applied in this study.

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

Renal impaired

Hepatic impaired

Pregnant women

Estimated number of subjects

1000

Study design details

Outcomes

To describe the frequency of off-label use among each of the subgroups of interest.

Data analysis plan

Descriptive statistics will be used including univariate analysis.

Documents

Study results

B010_Final_Report_Dulaglutide_PASS_DUS_FINAL_10.28.19_Redacted.pdf(4.42 MB)

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Sweden National Prescribed Drugs Register / Läkemedelsregistret

The Information System for Research in Primary Care (SIDIAP)

IQVIA Disease Analyzer Germany

Disease Analyzer - OMOP

Data sources (types)

Electronic healthcare records (EHR)

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