DARWIN EU® - Drug Utilisation Study on GLP-1 Receptor Agonists

First published: 20/06/2024

Last updated: 19/12/2024

Study Finalised

Administrative details

EU PAS number

EUPAS1000000223

Study ID

1000000223

DARWIN EU® study

Yes

Study countries

- [ ] Belgium
- [ ] Germany
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

Study description

A shortage of medicines containing GLP-1 Receptor Agonists is affecting EU Member States since 2022 and will continue throughout 2024. The shortage involves the medicinal products Ozempic (semaglutide), Victoza (liraglutide), Trulicity (dulaglutide) and Saxenda (liraglutide).

The shortage is based on an increased demand for these medicines in addition to other causes, e.g. capacity constraints.

Medicinal products belonging to the class of Glucagon-Like Peptide-1 receptor agonists (GLP-1 RA) are either authorised for the treatment of diabetes (Ozempic, Victoza, Trulicity, Bydureon, Rybelsus) or authorised for weight management (Saxenda, Wegovy); with the exception of Mounjaro (tirzepatide), a glucose-dependent insulinotropic polypeptide (GIP) and GLP-1 RA that is authorised for both indications. Of concern has been the off-label use of GLP-1 RAs for weight management which has been mentioned frequently in the news and social media and is exacerbating existing shortages with serious consequences for public health.

This study aims to provide an overview of the characteristics of patients prescribed with a GLP-1 RA medicinal product and how these have changed over the past ten years. This will help contextualise what determinants might be driving the demand for GLP-1 RA vis-à-vis the observed shortage of medicines, including exploring comparative trends of prescription of other medicinal products used in diabetes and for weight management as well as patterns of off-label use.

Study status

Finalised

Research institutions and networks

Institutions

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

☐ United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

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

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

☐ Belgium
☐ Croatia
☐ Denmark
☐ Estonia
☐ Finland
☐ France
☐ Germany
☐ Greece
☐ Hungary
☐ Italy
☐ Netherlands
☐ Norway

☐ Portugal

☐ Spain

☐ Sweden

☐ United Kingdom

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Marta Pineda Moncusi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/05/2024

Actual: 14/05/2024

Study start date

Planned: 01/07/2024

Actual: 14/05/2024

Date of final study report

Planned: 30/08/2024

Actual: 12/12/2024

Sources of funding

- EMA

Study protocol

DARWIN EU_D2.2.3_Protocol_P3-C1-008_GLP1_agonists shortages_V3 (1).pdf

(778.06 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study topic, other:

GLP-1 agonists shortage

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

Retrospective cohort studies will be conducted using routinely collected health data from five databases.

Main study objective:

This study aims to provide an overview of the characteristics of patients prescribed with a GLP-1 RA medicinal product and how these have changed over the past ten years.

The specific objectives of this study are:

1) To determine the incidence and prevalence of prescriptions of GLP-1 RA medicinal products (overall and stratified by age, sex, database, indications (only for incidence), and calendar time (per month), for the past 10 years.

Additionally, new drug users of GLP-1 RA (stratified by presence or absence of diagnosis of diabetes mellitus type 2 and diagnosis of obesity indications) will be characterised by age, sex, body mass index, initial dose, cumulative dose and a list of prespecified indications.

2) To determine the incidence and prevalence of prescriptions of medicines used for weight loss that help contextualise exposure to GLP-1 RA, including orlistat, naltrexone/bupropion, phentermine/topiramate, phentermine and metformin (overall and stratified by age, sex, database, and calendar time (per month), for the past 10 years.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

OZEMPIC

SAXENDA

TRULICITY

VICTOZA

Name of medicine, other

GLP-1 agonists

Study drug International non-proprietary name (INN) or common name

DULAGLUTIDE

LIRAGLUTIDE

SEMAGLUTIDE

Anatomical Therapeutic Chemical (ATC) code

(A10BJ) Glucagon-like peptide-1 (GLP-1) analogues

Glucagon-like peptide-1 (GLP-1) analogues

Population studied

Short description of the study population

Population-level drug utilisation of GLP-1 RA and medicines used for weight loss that help contextualise exposure to GLP-1 RA: All individuals present in the database in the last 10 years of available data will be included in the analysis. For this population, incidence and prevalence of use of GLP-1 RA and medicines used for weight loss that help contextualise exposure to GLP-1 RA will be explored.

Patient level cohort study on GLP-1 RA users stratified by presence or absence of diabetes mellitus type 2 and/or obesity: new drug users of GLP-1 RA stratified by presence or absence of diagnosis of diabetes mellitus type 2 and/or diagnosis of obesity will be characterised by age, sex, body mass index, initial dose, cumulative dose and a list of prespecified indications/comorbidities.

Documents

Study report

DARWIN EU_Report_P3-C1-008_GLP1RA_V4.pdf(6.31 MB)

Data management

Data sources

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

Integrated Primary Care Information (IPCI)

Clinical Practice Research Datalink (CPRD) GOLD

IQVIA Longitudinal Patient Data - Belgium

IQVIA Disease Analyzer Germany

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Not applicable