DARWIN EU® - Determinants for use of GLP1 receptor agonists – a drug utilisation study

First published: 10/11/2025

Last updated: 01/10/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000828

Study ID

1000000828

DARWIN EU® study

Yes

Study countries

- Belgium
- Croatia
- Denmark
- Finland

Germany
Netherlands
Norway
Spain
Sweden
United Kingdom

Study description

A shortage of medicines containing Glucagon-Like Peptide-1 receptor agonists (GLP-1 RA) has been affecting European Union (EU) Member States since 2022. The medicines belonging to the class of GLP-1 RA are either authorised for the treatment of diabetes or authorised for weight management in patients diagnosed with obesity, with the exception of Mounjaro (tirzepatide), a glucose-dependent insulinotropic polypeptide (GIP) and GLP-1 RA that is authorised for both indications.

Increased demand for these medicines has contributed to this shortage in addition to other causes, e.g.,

capacity constraints. Excessive off-label use for cosmetic weight loss of some of these medicines has raised

concerns.

This relates to use for weight management in people without obesity or people with overweight who do not have weight related health problems. This use 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 GLP-1 RA and to describe the pattern of use, including switching between GLP-1 RA substances and to other antidiabetics, as well as switching between selected brands. The study will span over 10 years, allowing for the assessment of potential changes in incidence of use, user characteristics, and treatment patterns.

This will help contextualise what determinants might be driving the demand for GLP-1 RA in relation to 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

Ongoing

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution **Educational Institution** **ENCePP partner**

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: 01/09/2025

Actual: 01/09/2025

Study start date
Planned: 28/11/2025

Actual: 28/11/2025

Date of final study report
Planned: 26/06/2026

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C2-013_014_021_RR GLP1 RA_V6.pdf (2.14 MB)

DARWIN EU_Protocol_P4-C2-013_RR GLP1 RA_V7.0.pdf (2.17 MB)

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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

1) To determine the incidence and prevalence of prescriptions of the GLP-1 RA medicines (overall, by ingredient, by pre-specified brand) during the last 10 years of available data, stratified separately by age, sex, indication (pre

defined presence or absence of diagnosis of type 2 diabetes mellitus and/or obesity) [only for incidence], and prescriber speciality (where available) [only for incidence], and by calendar month in each of the data sources.

2) To characterise new drug users of GLP-1 RA medicines (overall and stratified by ingredient, by brand, by indication cohorts [pre-defined presence or absence of diagnosis of type 2 diabetes mellitus and/or diagnosis of obesity) by age, sex, initial dose, cumulative dose, and a list of prespecified indications/comorbidities and related co-medications for each data source.
Characterisation will be done over the whole study period and by calendar year.

3) To describe GLP-1 RA switching of substances (exenatide, liraglutide, lixisenatide, dulaglutide, semaglutide, or tirzepatide cohorts) among new GLP-1 RA users for each data source [overall study period].

4) To describe GLP-1 RA within-substance switching of strength (limited to predefined cohorts of strength-levels, with brands when available, for liraglutide, dulaglutide, semaglutide, and tirzepatide) among new users of the respective medicine in each data source [overall study period].

5) To describe GLP-1 RA switching of substances (exenatide, liraglutide, lixisenatide, dulaglutide, semaglutide, or tirzepatide cohorts) among new GLP-1 RA users for each data source between 2015–2020 and annually between 2021 and 2025.

6) To describe GLP-1 RA within-substance switching of strength (limited to predefined cohorts of strength-levels, with brands when available, for liraglutide, dulaglutide, semaglutide, and tirzepatide) among new users of the respective medicine in each data source between 2015–2020 and annually

between 2021 and 2025.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

EXENATIDE

LIRAGLUTIDE

LIXISENATIDE

DULAGLUTIDE

SEMAGLUTIDE

TIRZEPATIDE

Anatomical Therapeutic Chemical (ATC) code

(A10BJ01) exenatide

exenatide

(A10BJ02) liraglutide

liraglutide

(A10BJ03) lixisenatide

lixisenatide

(A10BJ05) dulaglutide

dulaglutide

(A10BJ06) semaglutide

semaglutide

(A10BX16) tirzepatide

tirzepatide

Population studied

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

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)

Clinical Practice Research Datalink (CPRD) GOLD

Danish Health Data Registries

Integrated Primary Care Information (IPCI)

IQVIA Longitudinal Patient Data - Belgium

IQVIA Disease Analyzer Germany

The Information System for Research in Primary Care (SIDIAP)

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

Health Impact - Swedish Population Evidence Enabling Data-linkage

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

InGef Research Database

Norwegian Linked Health registry at University of Oslo

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

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

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No