NN2211-4077 Retrospective collection of effectiveness and safety data from patients treated with liraglutide or DPP-4 inhibitor in primary care in Europe

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Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS8135

Study ID

24533

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ Spain

United Kingdom

Study description

This study is conducted in Europe.The aim of this study is to demonstrate the clinical effectiveness and safety of liraglutide and dipeptidyl peptidase-4 (DPP-4) inhibitor therapy in routine primary care in Europe.

Study status

Finalised

Research institutions and networks

Institutions

Novo Nordisk

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Institution

Not applicable

Contact details

Study institution contact

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Study contact

pactadmin@novonordisk.com

Primary lead investigator

Global Clinical Registry (GCR, 1452) Novo Nordisk

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 18/01/2012

Study start date
Actual: 06/08/2013

Date of final study report
Actual: 09/03/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novo Nordisk A/S

Study protocol

4077-protocol-version-2-7-nw-redacted.pdf(392.69 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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To demonstrate the clinical effectiveness, safety and place in clinical practice of liraglutide and DPP-4 inhibitor therapy in routine primary care across Europe.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

LIRAGLUTIDE

DIPEPTIDYL PEPTIDASE 4

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

Consecutive patients with type 2 diabetes initiated on liraglutide or a DPP-4 inhibitor and primarily managed in primary care with 12 (-3/+6, e.g. 9 to 18) months of available data from UK, France, Germany and Spain.

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)

Special population of interest

Other

Special population of interest, other

Diabetes mellitus patients

Estimated number of subjects

952

Study design details

Outcomes

-Change in HbA1c (glycosylated haemoglobin), -Change in body weight-Change in systolic blood pressure

Data analysis plan

A full statistical analysis plan will be developed. In brief, we will undertake the testing of treatment difference using a linear mixed effects model with extend the mulilevel modeling to include center and country effects. Analysis will be adjusted for baseline demographic and risk factors profiles concordant with the data collected as specified in the study protocol.

Documents

Study results

4077-ctr-redacted.pdf(869.72 KB)

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 sources (types)

Other

Data sources (types), other

Retrospective

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