NN8022-4241 In-market utilisation of liraglutide used for weight management in Europe: a retrospective medical record review study

First published: 06/12/2016

Last updated: 14/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/35489

EU PAS number

EUPAS16225

Study ID

35489

DARWIN EU® study

No

Study countries

☐ Germany

☐ Italy

Study description

The aim of this study is to investigate usage of liraglutide for weight management in clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

Novo Nordisk

First published: 01/02/2024

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Institution

Multiple centres: 50 centres are involved in the study

Contact details

Study institution contact

Clinical Reporting Anchor and Disclosure (1452) Novo Nordisk A/S

Study contact

pactadmin@novonordisk.com

Primary lead investigator

Clinical Reporting Anchor and Disclosure (1452) Novo Nordisk A/S

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/02/2016

Actual: 25/02/2016

Study start date

Planned: 16/11/2016

Actual: 22/12/2016

Date of final study report

Planned: 31/05/2020

Actual: 04/10/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novo Nordisk

Study protocol

4241-protocol-redacted.pdf(526.16 KB)

4241-protocol-version-8.0-eu-pas-reg-redacted.pdf(476.15 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)

Other study registration identification numbers and links

U1111-1185-3661 (WHO)

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:

Secondary use of data

Main study objective:

To assess the use of Saxenda® according to the approved indication

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Post Authorisation Safety Study (PASS)

Study drug and medical condition

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

LIRAGLUTIDE

Medical condition to be studied

Obesity

Population studied

Short description of the study population

To be eligible for this full study, patients were required to meet both of the following inclusion criteria:

1. Initiation of Saxenda® or Victoza® (initiation is defined as no prescription of the same brand within the previous 12 months).

2. Informed consent obtained before any study-related activities. Study-related activities (e.g. data collection) are any procedures that are carried out as part of the study, including activities to determine suitability of the study.

Exclusion criteria:

1. Patients or physicians who previously participated in interventional programs for Saxenda® or Victoza® will not be eligible to participate in the study.

2. For the full study, sites and patients included in the pilot will be excluded.

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)

Estimated number of subjects

316

Study design details

Outcomes

Number of p with BMI above or equal to 30 kg/m^2Number of patients with BMI above or equal to 27kg/m^2 and below 30 kg/m^2 and 1 or more comorbidityNumber of patients with above or equal to 27 kg/m^2 and below 30 kg/m^2 and no comorbiditiesNumber of patients with BMI below 27 kg/m^2Number of patients with BMI not measured, See attached protocol

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Data analysis plan

As this is a descriptive study that will investigate in-market utilisation of liraglutide, no formal statistical testing will be conducted.

Documents

Study results

4241-nsr-nn-trials-redacted.pdf(1.13 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Retrospective abstraction of data from patient medical records

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