Active surveillance research program for the assessment of the safety and the effectiveness of linagliptin

First published: 29/07/2014

Last updated: 05/10/2026

Study Finalised

Administrative details

EU PAS number

EUPAS5790

Study ID

7474

DARWIN EU® study

No

Study countries

United States

Study description

This protocol is for a series of comparative effectiveness and safety analyses within periodically updated cohorts of patients initiating linagliptin, other DPP-4 inhibitors, and other oral hypoglycemic medications, followed longitudinally for the occurrence of a variety of health outcomes. The primary analysis will be conducted among patients without prior within-class medication use.

Study status

Finalised

Research institutions and networks

Institutions

Brigham and Women's Hospital

First published: 01/02/2024

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Institution

Contact details

Study institution contact

Sebastian Schneeweiss cgopalakrishnan@partners.org

Study contact

cgopalakrishnan@partners.org

Primary lead investigator

Sebastian Schneeweiss

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 28/12/2012

Actual: 28/12/2012

Study start date
Planned: 28/07/2014

Actual: 01/09/2014

Data analysis start date
Planned: 31/07/2014

Actual: 15/09/2014

Date of interim report, if expected
Planned: 31/10/2014

Date of final study report
Planned: 30/04/2018

Actual: 27/09/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

1218-0163_CTP_final-rule_Redacted.pdf (1.25 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

1218.163

NCT02197078

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

To conduct a multi-year research surveillance program that establishes and periodically updates initiator cohorts of linagliptin, within-class comparators (saxagliptin, sitagliptin, alogliptin), and out-of-class comparators (glitazones, 2nd generation of sulfonylureas (SUs)), and longitudinally follow them for the incidence of a variety of health outcomes.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Active surveillance, Sequential matched cohort study

Study drug and medical condition

Medicinal product name

TRAJENTA

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

LINAGLIPTIN

Anatomical Therapeutic Chemical (ATC) code

(A10BH05) linagliptin

linagliptin

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

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

120.000

Study design details

Outcomes

- Acute myocardial infarction- Coronary revascularization- Hemorrhagic stroke- Hospitalization for acute coronary syndrome- Ischemic stroke- Major adverse cardiovascular event (composite of coronary revascularization, hospitalization

for acute coronary syndrome, ischemic and hemorrhagic stroke), - Heart failure hospitalization - Incident End-Stage Renal Disease (ESRD) - Acute renal failure (ARF)- ARF that requires dialysis

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Data analysis plan

We will receive new data as they become available on a periodic basis (every 6 months) and, at each data cut, we will update the original set of data, form sequential cohorts by propensity score (PS) matching within 6-month blocks of time, follow patients for each of the outcomes of interest in a prospective manner, and estimate measures of effect using person-time based analyses among patients who initiate linagliptin versus a comparator drug. Unadjusted and adjusted relative risks (hazard ratios) and rate differences will be estimated. In adjusted analyses, we will use propensity score (PS) matching to balance potential confounders.

Documents

Abstract of study report

1218-0163_Synopsis.pdf (175.35 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)

Administrative healthcare records (e.g., claims)

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