Real world glycemic effectiveness of linagliptin (Tradjenta®) among type 2 diabetes mellitus adults by age and renal function.

First published: 14/11/2017

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Study Finalised

Administrative details

EU PAS number

EUPAS21548

Study ID

22317

DARWIN EU® study

No

Study countries

United States

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jeanine Cordova

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/06/2017

Study start date

Planned: 21/11/2017

Actual: 21/11/2017

Data analysis start date

Planned: 12/01/2018

Actual: 01/12/2017

Date of final study report

Planned: 30/03/2018

Actual: 04/02/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer-Ingelheim & Eli Lilly & Co

Study protocol

1218-0182_linagliptin-rwe-protocol-16-october-2017-final_final-rule_Redacted.pdf (364.61 KB)

1218-0182_protocol_SAP_redacted.pdf (364.61 KB)

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

1218-0182

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)

Data collection methods:

Secondary use of data

Study design:

This will be a non-interventional cohort study using existing data from patients in the Optum
Clinical Database which contains electronic health record (EHR) data from providers across
the United States.

Main study objective:

• Describe change in HbA1c among adults with T2DM w/in 60 to 180 days following initiation of linagliptin across pre-defined age and renal function categories.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective database study

Study drug and medical condition

Medicinal product name

TRAJENTA

Medicinal product name, other

Tradjenta

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

Short description of the study population

Patients with T2DM newly initiated on linagliptin, in the Optum electronic health record (EHR) database, aged 40 and older, and with HbA1c values during the both the 180 days before and the 60 to 180 days after starting linagliptin

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

Renal impaired

Estimated number of subjects

13.962

Study design details

Outcomes

change in (Glycosylatedhemoglobin)HbA1c, will beevaluated among the overallstudy sample and stratifiedacross pre-defined age andrenal function categories, Glycosylated hemoglobin(HbA1c) goal attainment, asdefined below, will beevaluated among the overallstudy sample and stratifiedacross pre-defined age andrenal function categories

Data analysis plan

Sample will be selected from national EMR database to produce generalizable estimates. The study will employ methods (e.g regression) to account for known confounding.

Documents

Study results

1218-0182_Synopsis.pdf (208.33 KB)

Data management

Data sources

Data source(s)

Optimum Patient Care Research Database

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

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