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

First published: 14/11/2017

Last updated: 16/01/2018

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/22317

EU PAS number

EUPAS21548

Study ID

22317

DARWIN EU® study

No

Study countries

United States

Study status

Ongoing

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Jeanine Cordova

Study contact

jeanine.cordova@boehringer-ingelheim.com

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

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer-Ingelheim & Eli Lilly & Co

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:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

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

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Age groups

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

13962

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.

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