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 status

Ongoing



Administrative details

EU PAS number	
EUPAS21548	
Study ID	
22317	
DARWIN FILS streets	
DARWIN EU® study	
No	
Study countries	
United States	

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

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 list

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 be evaluated among the overall study sample and stratified across pre-defined age and renal function categories, Glycosylated hemoglobin(HbA1c) goal attainment, as defined below, will be evaluated among the overall study sample and stratified across predefined age and renal 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

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 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