A description of oral and non-insulin injected hypoglycemic therapy utilization patterns including initiation, switching, and discontinuation (Non-insulin hypoglycemic therapy utilization)

First published: 22/05/2014

Last updated: 23/03/2015

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/9071

EU PAS number

EUPAS4373

Study ID

9071

DARWIN EU® study

No

Study countries

United States

Study description

This protocol is for a series of descriptive analyses conducted within a cohort of patients using linagliptin, other dipeptidyl peptidase-4 (DPP-4) inhibitors, and other oral and non-insulin injected hypoglycemic medications between May 2011 and June 2012.Understanding 1) the existing utilization patterns for linagliptin, sitagliptin, saxagliptin, and other oral and non-insulin injected hypoglycemic agents and (2) the differences in utilization patterns between these agents will help with the design, analysis and interpretation of comparative effectiveness and safety studies of linagliptin, other DPP-4 inhibitors, and other agents.The study will provide an overview of existing utilization patterns for linagliptin, other dipeptidyl peptidase-4 (DPP-4) inhibitors, other oral and non-insulin injected hypoglycemic agents, in order to detect potential selective prescribing patterns that might lead to channeling bias.

Study status

Finalised

Research institutions and networks

Institutions

Brigham and Women's Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Sebastian Schneeweiss

Study contact

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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: 26/05/2014

Actual: 01/06/2014

Data analysis start date

Planned: 01/07/2014

Actual: 01/07/2014

Date of interim report, if expected
Planned: 31/07/2014

Actual: 01/08/2014

Date of final study report
Planned: 30/09/2014

Actual: 04/12/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To understand (1)existing utilization patterns for linagliptin, other dipeptidyl peptidase-4 (DPP-4) inhibitors, other oral and non-insulin injected hypoglycemic agents, and (2) differences in utilization patterns between these agents to help with the design, analysis and interpretation of comparative effectiveness and safety studies of linagliptin, other DPP-4 inhibitors, and other agents.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10B) BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

Medical condition to be studied

Diabetes mellitus

Population studied

Short description of the study population

Patients with Diabetes mellitus aged 18 years and over

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

Other

Special population of interest, other

Diabetes mellitus patients

Estimated number of subjects

200000

Study design details

Outcomes

Primary outcomes are:- Proportion of initiators - Treatment switching- Treatment augmentation- Subsequent Insulin initiation, Secondary outcomes are:- Persistence at 12 months - Persistence at 3 months- Persistence at 6 months- Proportion of days covered- Treatment discontinuation

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Data analysis plan

Analyses are descriptive. Utilization patterns will be examined overall and in subgroups defined by patient characteristics, incident/former use, and over time. Adherence analyses will be conducted in propensity-score matched cohorts. The analyses will be based on May 2011 - June 2012 data.

Data management

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