Study Comparing Risk of Hospitalization for Heart Failure Between Dipeptidyl Peptidase-4 Inhibitors and Sulfonylureas

First published: 23/02/2015

Last updated: 02/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS8695

Study ID

8696

DARWIN EU® study

No

Study countries

☐ United States

Study description

Primary objective: To compare the risk of hospitalization for heart failure (hHF) between patients with type 2 diabetes mellitus (T2DM) treated with dipeptidyl peptidase-4 inhibitors (DPP-4is) vs. sulfonylureas (SUs)Secondary objectives:1. To compare the risk of hospitalization for acute myocardial infarction (AMI), hospitalization for stroke, hospitalization for unstable angina, coronary revascularization, and a composite of all aforementioned outcomes including hHF between patients with T2DM treated with DPP-4is vs. SUs2. To compare the risk of hHF between patients with T2DM treated with saxagliptin vs. sitagliptin or linagliptin 3. To compare the risk of hospitalization for AMI, hospitalization for stroke, hospitalization for unstable angina, coronary revascularization, and a composite of all aforementioned outcomes including hHF between patients with T2DM treated with saxagliptin vs. sitagliptin or linagliptinStudy designThis will be a retrospective, observational cohort study. This study will use as its methodological foundation, as closely as possible and appropriate, the approach that is outlined in the Mini-Sentinel protocol for active surveillance of AMI in association with use of anti-diabetic agents.

Study status

Ongoing

Research institutions and networks

Institutions

AstraZeneca

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Truven Health Analytics Bethesda, MD, USA,

Georgetown University Medical Center

Washington, DC, USA

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sheehan Jack

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/12/2014

Actual: 10/12/2014

Study start date

Planned: 06/01/2015

Actual: 06/01/2015

Data analysis start date
Planned: 26/02/2015

Date of interim report, if expected
Planned: 29/05/2015

Date of final study report
Planned: 26/06/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

HHF_Protocol_2015-02-23.pdf (216.25 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To compare the risk of hospitalization for heart failure between patients with type 2 diabetes mellitus treated with dipeptidyl peptidase-4 inhibitors vs. sulfonylureas

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ACETOHEXAMIDE

CHLORPROPAMIDE

GLIMEPIRIDE

GLIPIZIDE

NATEGLINIDE

REPAGLINIDE

TOLAZAMIDE

TOLBUTAMIDE

TOLBUTAMIDE SODIUM

Anatomical Therapeutic Chemical (ATC) code

(A10BH) Dipeptidyl peptidase 4 (DPP-4) inhibitors

Dipeptidyl peptidase 4 (DPP-4) inhibitors

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

533577

Study design details

Outcomes

Hospitalization for heart failure: events will be defined as inpatient admission with a principal discharge diagnosis for heart failure (ICD-9-CM 428.xx). Hospitalization for acute myocardial infarction, hospitalization for stroke, hospitalization for unstable angina, coronary revascularization, and a composite of all aforementioned outcomes including hHF (please see protocol for detailed codes and criteria)

Data analysis plan

Propensity scores will be (nearest neighbour technique and enforcing a caliper of 0.01 on the probability scale) derived from a logistic regression model including a wide variety of demographic, insurance, utilization, and clinical variables measured during the baseline period. Outcomes will be compared using bivariate Cox proportional hazards models (i.e. using the exposure of interest cohort membership indicator as the only independent variable) applied to the propensity score matched cohorts. In a sensitivity analysis for only the primary outcome of hHF, hHF will be compared using multivariable Cox proportional hazards models applied to the cohorts before matching. All statistical analyses will be separately conducted in patients with prior cardiovascular disease vs. patients without prior cardiovascular disease.

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), other

Truven Health Analytics MarketScan Research Databases United States

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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