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

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Study | Ongoing

## Administrative details

### Contact details

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**Primary lead investigator**
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**PURI**
https://redirect.ema.europa.eu/resource/8696

**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 institution and networks

## Institutions

### AstraZeneca
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Institution

### Truven Health Analytics Bethesda, MD, USA, Georgetown University Medical Center Washington, DC, USA

## Study timelines

**Date when funding contract was signed**

Planned:
10/12/2014
Actual:
10/12/2014

**Data collection**
Planned:
06/01/2015
Actual:
06/01/2015

**Start date of data analysis**
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**
100000094066
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

## Data sources

**Data source(s), other**
Truven Health Analytics MarketScan Research Databases United States

**Data sources (types)**
Administrative data (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