Non-interventional study on the effectiveness and safety of Empagliflozin compared with DPP-4 inhibitors in patients with type 2 diabetes in the United States

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## Administrative details

**Study description** 

EU PAS number	
EUPAS20677	
Study ID	
21657	
DARWIN EU® study	
No	
Study countries	
United States	

The main objective of the proposed study is to compare selected CV effectiveness outcomes in patients with T2DM initiating empagliflozin compared to propensity score (PS) matched patients with T2DM initiating a DPP-4 inhibitor in sequential analyses within periodically updated cohorts in the U.S., secondary objectives include other effectiveness outcomes, safety outcomes, and healthcare utilization outcomes.

#### **Study status**

Ongoing

## Research institutions and networks

### **Institutions**

## Brigham and Women's Hospital

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Institution

## Contact details

### **Study institution contact**

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Study contact

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**Primary lead investigator** 

### Elisabetta Patorno

**Primary lead investigator** 

# Study timelines

### Date when funding contract was signed

Planned: 01/12/2016

#### Study start date

Planned: 15/10/2017

Actual: 15/10/2017

#### Data analysis start date

Planned: 15/10/2017

Actual: 15/10/2017

### **Date of final study report**

Planned: 31/03/2022

# 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

#### 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)

Safety study (incl. comparative)

## Main study objective:

To compare selected CV effectiveness outcomes in patients with T2DM initiating empagliflozin compared to propensity score (PS) matched patients with T2DM initiating a DPP-4 inhibitor in sequential analyses within periodically updated cohorts in the U.S. secondary objectives include other effectiveness outcomes, safety outcomes, and healthcare utilization outcomes.

## Study Design

### Non-interventional study design

Cohort

Other

#### Non-interventional study design, other

Sequential matched cohort study

# Study drug and medical condition

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

**EMPAGLIFLOZIN** 

**SITAGLIPTIN** 

**SAXAGLIPTIN** 

LINAGLIPTIN

**ALOGLIPTIN** 

#### 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**

## Study design details

#### **Outcomes**

- 3-point MACE hospital admission for MI, hospital admission for stroke, CV mortality and its individual components- hospital admission for HF- all-cause mortality, - Coronary revascularization procedure - End-stage renal disease - Initiation of laser treatment for retinopathy- Bone fracture- Diabetic ketoacidosis- Severe hypoglycemia- All urinary tract cancers and its individual components, additional cancers may be considered.- Lower-limb amputation-Acute kidney injury requiring dialysis- Healthcare resource utilization- Cost

#### Data analysis plan

We will receive new data as they become available on a periodic basis (every 12 months) and, at each data cut, we will update the original set of data, form sequential cohorts by propensity score (PS) matching within 12-month blocks of time, follow patients for each of the outcomes of interest in a prospective manner, and estimate measures of effect using person-time based analyses among patients who initiate empagliflozin versus DPP-4 inhibitor use. Unadjusted and adjusted relative risks (hazard ratios) and rate differences will be estimated. In adjusted analyses, we will use propensity score (PS) matching to balance potential confounders.

## 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 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