Cardiovascular and renal outcomes, and mortality in Danish patients with type 2 diabetes who initiate empagliflozin versus GLP1-RA: A Danish nationwide comparative effectiveness study (EMPLACE)

First published: 04/06/2019

Last updated: 02/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS29985

Study ID

44917

DARWIN EU® study

No

Study countries

☐ Denmark

Study description

To compare, among patients with type 2 diabetes in Denmark, clinical outcomes among new users (initiators) of empagliflozin versus GLP1-RA. Our primary objective is to compare clinical outcomes (cardiovascular and renal outcomes and mortality) among empagliflozin initiators versus liraglutide and other GLP1-RA initiators in Denmark. This is a non-interventional cohort study using existing data. The study will use a new user design and compare new users of empagliflozin with new users of GLP1-RA. The study population will include all eligible patients with type 2 diabetes initiating treatment with empagliflozin or with GLP1-RA between 2015 and until 2020 or the latest date of data availability.

Study status

Ongoing

Research institutions and networks

Institutions

Aarhus University

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Institution

Aarhus University Hospital

Contact details

Study institution contact

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Primary lead investigator

Henrik Toft Sørensen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/12/2017

Actual: 05/12/2017

Study start date

Planned: 01/10/2018

Actual: 01/10/2018

Data analysis start date

Planned: 01/04/2019

Date of final study report

Planned: 31/01/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

RWE Empa and Lira.pdf(909.98 KB)

emplace-nis-study-protocol-version-03.pdf(359.73 KB)

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:

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

Our primary objective is to compare clinical outcomes (cardiovascular events, mortality) among empagliflozin initiators and liraglutide initiators in Denmark.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Nationwide population-based comparative effectiveness cohort study based on prospective medical databases in Denmark

Study drug and medical condition

Name of medicine, other

GLP1-RA class

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

EMPAGLIFLOZIN

LIRAGLUTIDE

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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

50000

Study design details

Outcomes

Primary outcome is a composite of hospitalization due to stroke, myocardial infarction, unstable angina, coronary revascularization, heart failure (HF), or all-cause death (expanded MACE). Secondary outcomes are first hospital admission with a diagnosis of HF and/or initiation of loop diuretics, hospital admission with HF and/or all-cause death, composite of all-cause hospitalization or death, all cause hospitalization, all-cause death, hospitalization for HF. In additional analyses, we will assess total healthcare resources utilization and cost.

Data analysis plan

We compute incidence rates of outcomes per 1,000 person-years (pyrs) and use Cox regression to compute adjusted hazard ratios (aHRs). We apply propensity score balancing of potential confounders across the two treatment groups by inverse probability treatment weighting (IPTW), controlling age, gender, year of inclusion, diabetes duration, number of diabetes drugs used, metformin use, insulin use, diagnoses of retinopathy, neuropathy, or nephropathy, estimated glomerular filtration rate (eGFR), history of ischemic heart disease, cerebrovascular disease, peripheral vascular disease, heart failure (further divided by duration and primary/secondary diagnosis), medical obesity, chronic obstructive pulmonary disease, cancer, use of angiotensin-converting-enzyme inhibitors (ACE-I) or angiotensin II receptor blockers (ARBs), other antihypertensives, statins, antiplatelet drugs, social and frailty markers, marital status, prescriptions for mental disorders, alcoholism, and prior admissions.

Documents

Study publications

Thomsen RW, Christensen LWB, Kahlert J, Knudsen JS, Ustyugova A, Sandgaard S, H...

Thomsen RW, Knudsen JS, Kahlert J, Baggesen LM, Lajer M, Holmgaard PH, Vedin O,...

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)

Danish registries (access/analysis)

Data source(s), other

Danish Registries (access/analysis)

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Other

Data sources (types), other

Nationwide health care databases

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