# 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.

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**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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Study 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

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**Study start date**

Planned: 01/10/2018

Actual: 01/10/2018

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**Data analysis start date**

Planned: 01/04/2019

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**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

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**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

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**Non-interventional study design, other**

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

## Study drug and medical condition

**Medicinal product name, other**

GLP1-RA class

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

EMPAGLIFLOZIN

LIRAGLUTIDE

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**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)

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**Special population of interest**

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

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**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.

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**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