Non-Interventional Study on the Side Effects of Empagliflozin Compared with DPP-4 Inhibitors in Patients with Type 2 Diabetes in New Zealand

First published: 14/09/2023

Last updated: 02/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS106713

Study ID

106714

DARWIN EU® study

No

Study countries

New Zealand

Study description

The purpose of this study is to compare the prevalence of the side effects of SGLT2 inhibitors in a large population of new users with type 2 diabetes (T2DM) in New Zealand compared to propensity score (PS) matched patients with T2DM initiating vildagliptin within the year 2021.

Study status

Ongoing

Research institutions and networks

Institutions

University of Auckland

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nataly Martini

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/04/2022

Study start date
Planned: 15/03/2023

Actual: 04/07/2023

Date of final study report
Planned: 31/03/2024

Sources of funding

- Other

More details on funding

The University of Auckland

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:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To compare the prevalence of side effects in patients with T2DM initiating empagliflozin compared to propensity score (PS) matched patients with T2DM initiating vildagliptin in New Zealand

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

EMPAGLIFLOZIN

VILDAGLIPTIN

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

78406

Study design details

Outcomes

acute kidney injury, lower limp amputation, urinary tract infection, genital mycotic infection, pancreatitis, venous thromboembolism, diabetic ketoacidosis, and Fournier’s gangrene

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Data analysis plan

Baseline characteristics will be compared between the treatment groups. Multivariable logistic regression analysis will be performed to compare the occurrence of side effects between the two groups, adjusting for potential confounding factors. Users of empagliflozin will be matched with users of vildagliptin at a 1:1 ratio. Propensity scores will be calculated to match the confounders using the nearest neighbour method.

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