Investigating risk of cancer with Sodium-glucose cotransporter 2 inhibitors: a Case/Non-Case Study in the WHO Global Pharmacovigilance Database Vigibase

First published: 03/09/2024

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000311

Study ID

1000000311

DARWIN EU® study

No

Study countries

France

Study description

Disproportionnality analysis using the WHO global database Vigibase.

Study status

Finalised

Research institutions and networks

Institutions

Toulouse University Hospital

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Institution

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 01/02/2024

Actual: 01/02/2024

Study start date

Planned: 01/02/2024

Actual: 01/02/2024

Data analysis start date

Planned: 01/03/2024

Actual: 01/03/2024

Date of final study report

Planned: 01/07/2024

Actual: 01/07/2024

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Study design:

Disproportionnality analysis on the WHO global database Vigibase.

Main study objective:

Exploratory analysis in the WHO's global pharmacovigilance database, Vigibase, to search for main cancers risk signals associated with the use of SGLT-2i.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case non-case design (disproportionnality analysis)

Study drug and medical condition

Medicinal product name

DAPAGLIFLOZIN

Medicinal product name, other

Canagliflozin, Empagliflozin

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

CANAGLIFLOZIN

DAPAGLIFLOZIN

EMPAGLIFLOZIN

Anatomical Therapeutic Chemical (ATC) code

(A10BK) Sodium-glucose co-transporter 2 (SGLT2) inhibitors

Sodium-glucose co-transporter 2 (SGLT2) inhibitors

(A10BK01) dapagliflozin

dapagliflozin

(A10BK02) canagliflozin

canagliflozin

(A10BK03) empagliflozin

empagliflozin

Additional medical condition(s)

Cancer

Population studied

Short description of the study population

Adults > 18 years old exposed to SGLT-2i or other oral antidiabetic drugs (GLP1 analogues and DPP4 inhibitors) in Vigibase between 2014 and 2023

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)

        - Adults (18 to < 46 years)
        - Adults (46 to < 65 years)
    - Elderly (≥ 65 years)
        - Adults (65 to < 75 years)
        - Adults (75 to < 85 years)
        - Adults (85 years and over)

Study design details

Setting

All ICSR between 01/01/2014 and 31/12/2023 were included. Patients 18 years old or older will be included. Cases are each subtype of cancer and non cases are all other ICSRs of the database. Exposed patients are ICSR with SGLT-2i (empagliflozin, dapagliflozin, canagliflozin) as suspected drug, controls are ICSR with GLP-1 analogues or DPP4 inhibitors as suspected drug.

Comparators

Patients exposed to GLP-1 analogues or DPP4 inhibitors

Outcomes

Reprorting Odds Ratios for cancers (overall) and each cancer taken individually.

Data analysis plan

The characteristics of the subjects in both groups will be described using frequencies and percentages. The disproportionality in cancer reporting between the exposed and non-exposed groups will be analyzed by calculating the Reporting Odds Ratio (ROR) through logistic regression with adjustments for age, sex, reporting country, and co-prescriptions with carcinogenic risk. The signal will be considered significant if the lower bound of the 95% confidence interval (CI95%) is greater than 1.

Data management

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), other

WHO global pharmacovigilance database Vigibase

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

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