How many and who are patients with heart failure eligible to SGLT2 inhibitors? Responses from the combination of administrative healthcare and primary care databases

First published: 15/07/2024

Last updated: 15/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000259

EU PAS number

EUPAS1000000259

Study ID

1000000259

DARWIN EU® study

No

Study countries

☐ Italy

Study description

Background: Recent successful findings (i.e. DAPA-HF trial) in patients with heart failure (HF) with/without diabetes treated with sodium-glucose co-transporter inhibitors (SGLT2-I) have fostered real-world data analyses. Fondazione Ricerca e Salute's (ReSD) administrative and Health Search's (HSD) primary healthcare databases were combined in the ReS-HS DB Consortium, to identify and characterize HF-patients eligible to SGLT2-I, and assess their costs charged to the Italian National Health Service (INHS).

Methods and results: Eligibility to SGLT2-I was HF diagnosis, age ≥ 18 years, reduced (≤40%) ejection fraction (HFrEF) and glomerular filtration rate (GFR) ≥30 ml/min. The HSD, including 13,313 HF-patients (1.5% of the total HSD population) was used to develop and test the algorithms for imputing HFrEF and GFR ≥ 30 ml/min, based on a set of covariates, to the ReSD, including 67,369 (1.5% of the total ReSD population). Subjects eligible to SGLT2-I were 2187 in HSD (61.1% of HFrEF); after the imputation, 15,145 in ReSD (58.8% of HFrEF). Prevalence of eligibility to SGLT2-I was higher in males then in females and increased with age; diabetic patients were 44.3% and 33.4% of HSD and ReSD populations eligible to SGLT2-I, respectively. Estimated from ReSD, the mean annual cost charged to the INHS per patient with HF eligible to SGLT2-I was €7122 (68% due to hospitalizations).

Conclusions: Approximately 20% of patients with HF was eligible to SGLT2-I. Real-world data can identify,
quantify and characterize patients eligible to SGLT2-Is and assess related costs for the health care system, thus
providing useful information to Regulatory Decision makers.

Study status

Finalised

Research institutions and networks

Institutions

Fondazione ReS (Ricerca e Salute), CINECA partner

Italy

First published: 05/07/2017

Last updated: 12/04/2024

Institution | Not-for-profit | ENCePP partner

Health Search, Italian College of General Practicioners

Italy

First published: 02/03/2010

Last updated: 20/08/2024

Institution | Educational Institution | Other

Contact details

Study institution contact

Carlo Piccinni

Study contact

piccinni@fondazioneres.it

Primary lead investigator

Letizia Dondi

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 12/01/2022

Study start date
Actual: 10/02/2022

Date of final study report
Actual: 02/04/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astra Zeneca SpA

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Healthcare resource utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

Retrospective longitudinal cohort study

Main study objective:

To identify and characterize HF-patients eligible to SGLT2-I, and assess their costs charged to the Italian National Health Service (SSN)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

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

Sodium-glucose co-transporter 2 (SGLT2) inhibitors

Medical condition to be studied

Cardiac failure

Population studied

Short description of the study population

Patients with HF eligible to the SGLT2-Is dapagliflozin, regardless of diabetes (according to the DAPA-HF trial's eligibility criteria) were identified from the Health Search primary care database and from the Fondazione ReS administrative database

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Age groups

Adult and elderly population (≥18 years)

Study design details

Setting

In-hospital and local outpatient setting in public and affiliated with SSN facilities, as regards the Database of Fondazione ReS.

Primary care as regards the Health Search database

Summary results

The HSD, including 13,313 HF-patients (1.5% of the total HSD population) was used to develop and test the algorithms for imputing HFrEF and GFR ≥ 30 ml/min, based on a set of covariates, to the ReSD, including 67,369 (1.5% of the

total ReSD population). Subjects eligible to SGLT2-I were 2187 in HSD (61.1% of HFrEF); after the imputation, 15,145 in ReSD (58.8% of HFrEF). Prevalence of eligibility to SGLT2-I was higher in males then in females and increased with age; diabetic patients were 44.3% and 33.4% of HSD and ReSD populations eligible to SGLT2-I, respectively. Estimated from ReSD, the mean annual cost charged to the INHS per patient with HF eligible to SGLT2-I was €7122 (68% due to hospitalizations).

Documents

Study publications

How many and who are patients with heart failure eligible to SGLT2 inhibitors?…

Data management

Data sources

Data source(s)

Database of Fondazione ReS

Health Search/IQVIA Health Longitudinal Patient Database

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes