Chronic Kidney Disease Eligible for SGLT2 Inhibitors Through the Integration of Italian Administrative and Primary Care Data

First published: 17/07/2024

Last updated: 17/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS1000000269

Study ID

1000000269

DARWIN EU® study

No

Study countries

☐ Italy

Study description

Patients with chronic kidney disease (CKD) can be successfully treated with sodium-glucose cotransporter-2 inhibitors (SGLT2-Is), regardless of diabetes. Fondazione Ricerca e Salute's (ReSD) administrative and Health Search's (HSD) primary care databases were combined in the Database Consortium ReS-HS to quantify and describe patients with CKD potentially eligible for SGLT2-Is and assess costs charged to the Italian National Health Service (SSN). Patients aged ≥18 with CKD and estimated glomerular filtration rate (eGFR) <60 ml/min in 2018, without dialysis and/or renal transplantation, were included. HSD was used to develop and validate algorithms for estimating eGFR, based on covariates, within the ReSD. Comorbidities, dispensed drugs, and direct healthcare costs were assessed. In 2018, 66,297 (5.0% of HSD population) and 211,494 (4.4% of ReSD population) patients with CKD potentially eligible for SGLT2-Is were identified (females ≥58%). Prevalence increased with age with a peak at 75-84 years. Within HSD and ReSD cohorts, respectively: 31.0% and 41.5% had diabetes; in the observation periods, >82% and >96% received ≥1 pharmacological treatment, of which ≥50% and ≥25% received cardiovascular/blood agents and antidiabetics, respectively. From ReSD, mean per capita direct SSN cost was € 3,825 (CI 95%, € 3,655-€ 4,000): 50.1% due to hospitalizations, and 40.2% to pharmaceuticals (31.6% to cardiovascular drugs and 10.1% to antidiabetics).

Study status

Finalised

Research institutions and networks

Institutions

Health Search, Italian College of General Practicioners

Italy

First published: 02/03/2010

Last updated: 20/08/2024

Institution | Educational Institution | Other

Fondazione ReS (Ricerca e Salute), CINECA partner

Italy

First published: 05/07/2017

Last updated: 12/04/2024

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Letizia Dondi

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 16/10/2022

Study start date
Actual: 16/03/2023

Date of final study report
Actual: 16/07/2023

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 type

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Study design:

Retrospective longitudinal cohort study

Main study objective:

To quantify and describe patients with CKD potentially eligible for SGLT2-Is and assess costs charged to the Italian National Health Service (SSN).

Study Design

Non-interventional study design

Cohort

Cross-sectional

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

Chronic kidney disease

Population studied

Short description of the study population

Among patients aged ≥18, alive by the end of 2018 and analyzable until 2013, with CKD and potentially eligible for SGLT2-Is

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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

In-hospital and local outpatient setting in public and affiliated with SSN facilities for the database of Fondazione ReS. Primary care for the Health Search

database

Summary results

In 2018, 66,297 (5.0% of HSD population) and 211,494 (4.4% of ReSD population) patients with CKD potentially eligible for SGLT2-Is were identified (females ≥58%). Prevalence increased with age with a peak at 75-84 years. Within HSD and ReSD cohorts, respectively: 31.0% and 41.5% had diabetes; in the observation periods, >82% and >96% received ≥1 pharmacological treatment, of which ≥50% and ≥25% received cardiovascular/blood agents and antidiabetics, respectively. From ReSD, mean per capita direct SSN cost was € 3,825 (CI 95%, € 3,655-€ 4,000): 50.1% due to hospitalizations, and 40.2% to pharmaceuticals (31.6% to cardiovascular drugs and 10.1% to antidiabetics).

Documents

Study publications

Chronic Kidney Disease Eligible for SGLT2 Inhibitors Through the Integration of…

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