FINErenone druG Utilization Study and assessment of Temporal changes following availability of different treatment options in patients with chronic kidney disease and type 2 diabetes (FINEGUST)

First published: 22/08/2022
Last updated: 29/03/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/49285

EU PAS number
EUPAS48148

Study ID
49285

DARWIN EU® study
No

Study countries
Denmark
Japan
Netherlands
Spain
United Kingdom
United States

Study description
This is an observational study in people with chronic kidney disease (CKD) and type 2 diabetes (T2D) who have already started or will start one of the following treatments for T2D or CKD: Sodium-glucose cotransporter 2 inhibitors (SGLT2i), Glucagon-like peptide-1 receptor agonists (GLP-1 RA), Steroidal mineralocorticoid receptor antagonists (sMRA), Finerenone a non-steroidal mineralocorticoid receptor antagonist (nsMRA), Other nsMRA (only in Japan). The main purpose of the study is to collect and describe characteristics of patients in each treatment group before and after finerenone became available. To do this, the researchers will collect data on: • Patient characteristics (e.g., age sex) of the participants • Clinical characteristics (e.g., history of CKD and T2D, heart and liver health, other health problems) of the participants • Treatments for T2D and CKD • Other medications used Data will be grouped by type of treatment that is initiated (e.g., SGLT2i, a GLP-1 RA, a sMRA, finerenone, or other nsMRA). Two time periods will be compared. Period I is the time until finerenone became available in the respective country, starting from 2012 (2014 for Japan). Period II will begin when finerenone becomes available in the respective country and will end at the end of the study (planned in September 2024). Researchers will also collect data on treatment patterns and changes in baseline characteristics in both time periods. Existing health care data will be collected from various sources in six countries (e.g., Denmark, Japan, the Netherlands, Spain, UK, and US). Besides this data collection, no further tests or examinations are planned in the study. The patients will receive their treatment as prescribed by their doctors during routine practice. Each patient will be in the study from first use of one of the listed drug classes until: • End of study • The data are somehow no longer available • The patient leaves or has to leave the study

Study status
Ongoing

Research institution and networks

Institutions

RTI Health Solutions (RTI-HS)
France
Spain
Sweden
United Kingdom
United Kingdom (Northern Ireland)
United States
First published: 21/04/2010
Last updated 19/02/2024
Institution

Not-for-profit

ENCePP partner

Optum

Germany
First published: 03/01/2012
Last updated
07/02/2014

Institution

ENCePP partner

Other

Clinical Practice Research Datalink (CPRD)

United Kingdom
First published: 15/03/2010
Last updated
02/07/2019

Institution

ENCePP partner

Laboratory/Research/Testing facility

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark
First published: 20/07/2021
Last updated
02/04/2024

Institution

ENCePP partner

Educational Institution

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands
First published: 07/01/2022
Last updated
10/01/2022

Institution

Laboratory/Research/Testing facility

ENCePP partner

The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

Spain
First published: 01/02/2024
Last updated 01/02/2024

Institution

FISABIO Spain, The Japan Chronic Kidney Disease Database Extension Japan, Optum Clinformatics® DataMart US

Contact details

Study institution contact
Bayer Clinical Trials BAYER AG

Study contact

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Primary lead investigator
Catherine Johannes

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
31/05/2022
Actual:
06/05/2022

Study start date
Planned:

01/10/2022
Actual:
01/10/2022

Date of final study report
Planned:
31/12/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

21956_FINEGUST_Protocol_Redacted_v1.0_2022-05-30.pdf(812.13 KB)

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 type:
Non-interventional study

Scope of the study:
Drug utilisation

Main study objective:
The primary objective of this study is to describe baseline patient characteristics, comorbidities, and comedication of adult patients with CKD and T2D who initiate an SGLT2i, a GLP-1 RA, a MRA, or finerenone in each of 2 time periods corresponding to the finerenone pre-launch and post-launch dates.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(C03DA05) finerenone

Medical condition to be studied
Chronic kidney disease
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)

Special population of interest
Renal impaired

Estimated number of subjects
50000

Study design details

Outcomes
• Descriptive summary of baseline patient characteristics • Descriptive summary of patient comorbidities • Descriptive summary of patient comedications, • Descriptive summary of changes over time in treatments in the new-user cohorts • Descriptive summary of temporal changes in the baseline characteristics of medication-specific cohorts

Data analysis plan
Descriptive analyses of patient characteristics and treatment patterns.

Data management

Data sources

Data source(s)
Clinical Practice Research Datalink
PHARMO Data Network

Data source(s), other
Danish National Health Registers Denmark, Valencia Health System Integrated Database Spain, Japan Chronic Kidney Disease Database Extension Japan, Optum Clinformatics® DataMart United States

Data sources (types)
Administrative data (e.g. claims)
Disease registry
Electronic healthcare records (EHR)
Other

Data sources (types), other
Prescription event monitoring

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