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: 04/09/2025

Study Finalised

Administrative details

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

Finalised

Research institutions 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: 11/08/2026

Institution **Not-for-profit** **ENCePP partner**

Optum

Germany

First published: 03/01/2012

Last updated: 07/02/2014

Institution | Outdated | Other | ENCePP partner

Clinical Practice Research Datalink (CPRD)

United Kingdom

First published: 15/03/2010

Last updated: 17/01/2025

Institution | Laboratory/Research/Testing facility | ENCePP partner

Aarhus University & Aarhus University Hospital CLINICAL EPIDEMIOLOGY AND DATA SCIENCE, DEPARTMENT OF CLINICAL MEDICINE

Denmark

First published: 20/07/2021

Last updated: 20/10/2026

Institution | Educational Institution

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

First published: 07/01/2022

Last updated: 19/12/2025

Institution | Non-Pharmaceutical company | ENCePP partner

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

Spain

First published: 01/02/2024

Last updated: 31/10/2025

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 clinical-trials-contact@bayer.com

Study contact

clinical-trials-contact@bayer.com

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

Actual: 06/03/2025

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 topic:

Disease /health condition

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

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

FINERENONE

Anatomical Therapeutic Chemical (ATC) code

(C03DA05) finerenone

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

50.000

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

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Data analysis plan

Descriptive analyses of patient characteristics and treatment patterns.

Documents

Study results

21956_EU PAS Abstract_Redacted_V1_06_Mar_2025.pdf (187.71 KB)

Study report

21956_FINEGUST Final Report_v1.0_06 MAR 2025_for publication.pdf (5.76 MB)

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 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 healthcare records (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