An Observational Study to Learn More About How Safe Finerenone is and How Well it Works in People with Chronic Kidney Disease and Type 2 Diabetes in Routine Medical Care in the United States

First published: 23/09/2024

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000231

Study ID

1000000231

DARWIN EU® study

No

Study countries

☐ United States

Study description

This is an observational study in which data from people with chronic kidney disease (CKD) and Type 2 diabetes mellitus (T2D) are collected and studied.
In observational studies, only observations are made without participants receiving any advice or any changes to healthcare.
CKD is a long-term condition in which the kidneys' ability to work properly gradually decreases over time. It is common in people with Type 2 diabetes mellitus (T2D), a condition in which glucose levels rise in the blood. People who have T2D and CKD may also develop heart disease over time.
The study drug, finerenone, is already approved for doctors to prescribe to people with CKD and T2D in the US. It blocks the activity of a protein involved in worsening kidney function.
The participants in this study are allowed to take finerenone as part of their regular care from their doctors.
The main purpose of the study is to learn about how safe finerenone is and how well it works in people with CKD and T2D in routine medical care. To do this, researchers will collect information about the time to first occurrence of any of the following heart-related problems for participants in the US who are taking finerenone and those who are not taking it:

- Heart attacks
- Hospitalization due to heart failure

The data will come from the electronic healthcare records of people with CKD and T2D in the US who are allowed to take finerenone after July 2021.
Researchers will track participants' data and will follow them until the occurrence of heart-related problems, the participant's data is no longer available, there is a change in the participant's treatment strategy, or the end of the study.
In this study, only available data from routine care are collected. No visits or tests are required as part of this study.

Study status

Ongoing

Research institutions and networks

Institutions

Bayer AG

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Institution

Networks

HealthVerity® Chronic Kidney Disease Masterset, US RTI-HS, Barcelona, Spain

Contact details

Study institution contact

Bayer Clinical Trials Contact clinical-trials-contact@bayer.com

Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trails Contact BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/03/2024

Actual: 14/03/2024

Study start date

Planned: 10/10/2024

Actual: 10/09/2024

Date of final study report

Planned: 31/03/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

22663_Study Protocol_Redacted_V2.0_2024-07-03.pdf(1.21 MB)

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:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

To assess the effectiveness of finerenone by estimating the risk of a composite cardiovascular outcome (i.e., first occurrence of fatal or nonfatal acute myocardial infarction or hospitalisation for heart failure) in patients with CKD and T2D initiating finerenone compared with that in patients with CKD and T2D not using finerenone.

Study drug and medical condition

Name of medicine

KERENDIA

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

Short description of the study population

Patients with CKD and T2D initiating finerenone and patients with CKD and T2D not using finerenone. This study will be conducted using existing healthcare data from the US. Considered data sources include the HealthVerity® Chronic Kidney Disease Masterset.

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)

Estimated number of subjects

150000

Study design details

Outcomes

Primary Outcomes:

Time to the first occurrence of composite cardiovascular outcome.

Secodary Outcomes:

Time to the first occurrence of an inpatient hospital diagnosis of fatal or nonfatal acute myocardial infarction.

Time to the first occurrence of an inpatient hospitalisation with a primary diagnosis of heart failure.

Time to the first occurrence of an inpatient hospital or emergency department diagnosis of heart failure for participants without a history of heart failure.

Time to occurrence of specific Urine Albumin-Creatine Ratio (UACR) decline thresholds.

Time to the first occurrence of a hospitalisation or emergency department visit with a diagnosis code for hyperkalaemia.

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.

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