

# 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

**Last updated:** 31/12/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000231

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### Study ID

1000000231

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### DARWIN EU® study

No

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### Study countries

 United States

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## **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.

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## **Study status**

Ongoing

## Research institutions and networks

### Institutions

**Bayer AG**

**First published:** 01/02/2024

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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](mailto:clinical-trials-contact@bayer.com)

**Study contact**

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**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

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### Study start date

Planned: 10/10/2024

Actual: 10/09/2024

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### 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

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## Is the study required by a Risk Management Plan (RMP)?

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Human medicinal product

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#### **Study type:**

Non-interventional study

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#### **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

**Medicinal product name**

KERENDIA

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

FINERENONE

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**Anatomical Therapeutic Chemical (ATC) code**

(C03DA05) finerenone

finerenone

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**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.

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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)
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### **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No