FINE-REAL: Non-interventional study to collect real-world data and providing insights into the use of finerenone in routine clinical practice

First published: 05/04/2022

Last updated: 06/11/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS46493

Study ID

50075

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Belgium
- [ ] Brazil

- [ ] Canada
- [ ] China
- [ ] Denmark
- [ ] Germany
- [ ] Greece
- [ ] Korea, Republic of
- [ ] Mexico
- [ ] Netherlands
- [ ] Portugal
- [ ] Saudi Arabia
- [ ] Singapore
- [ ] Slovenia
- [ ] Switzerland
- [ ] Taiwan
- [ ] Thailand
- [ ] United States

Study description

The main purpose of the study is to learn more about treatment patterns in people with CKD and T2D who will start finerenone treatment as decided and prescribed by their doctor as part of their routine medical care. To answer this question, the researchers will collect data on: • Clinical characteristics (e.g., history of CKD and T2D, blood pressure, heart health) of the participants • Reasons for starting finerenone • Reasons for stopping finerenone early • How long participants have been taking finerenone (planned by their doctor compared to actual time it was taken) • Dosing of finerenone • Other medications used while taking finerenone The researchers will also collect data on medical problems (called adverse events) that the participants may have during the study. All adverse events are collected, even if they might not be related to the study treatment. Hyperkalemia, a medical term used to describe

a potassium level in the blood that is higher than normal, is of special interest when finerenone is combined with some medications commonly taken to control blood pressure. Researchers want to know how often higher potassium levels occur, and when it leads to: • Stopping finerenone treatment too early • Dialysis (a medical procedure to filter the blood of extra water and waste) • Care in a hospital All data will come from medical records or from interviews study doctors will have with the participants during visits that take place during routine medical care. Participants in the US will be invited to provide voluntary blood and urine samples that could be analyzed later to better understand possible changes in protein or nucleic acid levels over time. Each participant will be in the study for 12 months. This time participating in the study may be shorter if their finerenone treatment is stopped early or the study comes to an end as planned in November 2025.

Study status

Ongoing

Research institutions and networks

Institutions

Bayer AG

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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

Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials Contact BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/02/2022

Study start date

Planned: 08/06/2022

Actual: 13/06/2022

Date of final study report

Planned: 30/06/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

21785 FINE-REAL_Protocol_V1.0_09 FEB 2022_Redacted.pdf(716.86 KB)

21785 FINE-REAL Protocol_V5.0_8Jul2024.pdf(866.95 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

NCT05348733

NCT05348733

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

The primary objective in this study is to describe treatment patterns in participants with CKD and T2D treated with finerenone in routine clinical practice.

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

Diabetic nephropathy

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

4500

Study design details

Outcomes

1.Descriptive analysis of clinical characteristics of participants with CKD and T2D. 2.Descriptive summary of reasons for introducing & discontinuation of finerenone 3.Planned and actual duration of treatment with finerenone 4.Descriptive summary of dose & frequency of finerenone treatment. 5.Descriptive summary of secondary therapies used in participants with CKD and T2D, 1.Occurrence of adverse events (AEs) and serious adverse events (SAEs) 2.Occurrence of hyperkalemia, - leading to permanent study drug discontinuation. - leading to dialysis - leading to hospitalization

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Data analysis plan

Statistical analyses will be of explorative and descriptive nature. The study is not intended to test pre-defined statistical hypotheses. All variables will be analyzed descriptively with appropriate statistical methods. All analyses will be performed for the total study population (overall population) and separately for

each participating country if patient numbers are sufficient and if required for local reasons. All analyses will be performed for the total study population (overall population) and separately for each participating country if patient numbers are sufficient and if required for local reasons. Interim analysis will consist of demographic and baseline data of patients enrolled as well as available safety data.

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 sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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