WINE Study: Roxadustat Treatment of Anemia of Chronic Kidney Disease (CKD) in Real-world Clinical Practice - Observational Study Utilizing Routinely Collected Secondary Data from WiNe Registry in Germany

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000121

Study ID

1000000121

DARWIN EU® study

No

Study countries

Germany

Study description

Erythropoiesis-stimulating agents (ESAs) and intravenous (IV) iron have been the standard of care for anemia of chronic kidney disease (CKD) for over 30 years, whereas roxadustat (EVRENZO) was only approved by the European Medicines Agency (EMA) on 18 August 2021 for the treatment of anemia of CKD.

The clinical trial program for roxadustat provides robust evidence of the clinical efficacy and safety of roxadustat in relation to placebo and standard of care. However, there is a need to generate real-world clinical evidence that better reflects the actual clinical environment in which roxadustat will be used in terms of patient demographics, comorbidities, adherence, and concurrent treatments.
Such data will be a valuable complement to that gathered in clinical trials.

Study status

Finalised

Research institutions and networks

Institutions

Astellas Pharma Europe Ltd.

Contact details

Study institution contact

Clinical Trial Registration Department

clinicaltrialregistration@astellas.com

Study contact

clinicaltrialregistration@astellas.com

Primary lead investigator

Dr. Frank-Peter Tilmann

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/11/2023

Actual: 08/11/2023

Study start date

Actual: 04/04/2024

Data analysis start date

Planned: 25/10/2024

Actual: 19/09/2024

Date of final study report

Planned: 30/04/2025

Actual: 09/04/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astellas Pharma Europe Ltd.

Study protocol

1517-ma-3501-original-protocol-disclosure-redacted.pdf (1.78 MB)

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

1517-MA-3501

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

To generate real-world evidence that better reflects the actual clinical environment in which roxadustat will be used.

Data collection methods:

Secondary use of data

Study design:

This is an observational cohort study using routinely collected secondary data of patients with anemia of CKD, newly treated with roxadustat or treated with ESA, identified from the WiNe registry between August 2021 and 6 months before the end of available data.

Main study objective:

The primary objectives of this study are to describe the characteristics and comorbidities of patients with CKD newly treated with roxadustat and how these differ when patients are stratified by dialysis status and by prior ESA use. In addition, the study will describe the clinical outcomes in patients treated with roxadustat for the management of anemia of CKD, both overall and when stratified by dialysis status and by prior ESA use.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

EVRENZO

Medicinal product name, other

Erythropoiesis-stimulating agents (ESA)

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

DARBEPOETIN ALFA

EPOETIN BETA

METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA

ROXADUSTAT

Anatomical Therapeutic Chemical (ATC) code

(B03XA01) erythropoietin

erythropoietin

(B03XA02) darbepoetin alfa

darbepoetin alfa

(B03XA03) methoxy polyethylene glycol-epoetin beta

methoxy polyethylene glycol-epoetin beta

(B03XA05) roxadustat

roxadustat

Medical condition to be studied

Chronic kidney disease

Anaemia

Population studied

Short description of the study population

Patients included in this study will be adults with symptomatic anemia of CKD (all stages) requiring treatment with roxadustat or an ESA, irrespective of dialysis status.

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)

Special population of interest

Renal impaired

Estimated number of subjects

180

Study design details

Outcomes

Primary outcomes include the following:

• Characteristics: Age at index date (defined as the date of the first recorded prescription of either roxadustat or ESA), sex, time since CKD diagnosis, anemia

and time since anemia diagnosis, body mass index (BMI), primary cause of CKD, stage of CKD at diagnosis and at index, dialysis status/type of dialysis at index, roxadustat initiation dose at index, inflammatory status, Hb level, iron status (ferritin/serum iron/TSAT/TIBC), PTH levels, renal function (eGFR and albumin/creatinine ratio levels for NDD patients), and use of oral and IV iron treatment at baseline.

• Comorbidities: e.g., diabetes mellitus, hypertension, congestive heart failure, ischemic heart disease, cerebrovascular disease including stroke, peripheral vascular disease, pulmonary embolism, deep vein thrombosis, vascular access thrombosis, seizures, sepsis, history of cancer/malignancy, chronic inflammatory disease, history of transplants. [The details of reporting of comorbidities will be ascertained at analysis stage].

• Medications: RAASi and SGLT2i.

• Mean dose of roxadustat at initiation, mean dose of roxadustat over time and mean maintenance dose.

• Responsiveness to treatment at specific intervals: time to meet Hb target threshold, proportion of patients achieving Hb target threshold; mean change of Hb, mean change in eGFR and albumin/creatinine ratio levels from baseline for NDD patients; ferritin, TSAT, TIBC, serum iron levels; CRP levels; time to first IV iron treatment from index date; IV iron dose and number of IV iron administrations; time to rescue therapy (ESA); mean PTH levels

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Data analysis plan

No hypothesis will be tested in this study as it is a descriptive, non-interventional retrospective study.

Patients will be stratified based on their prescription records during the identification period into 2 exposure groups, roxadustat exposure group or ESA exposure group.

Data for each exposure group will be summarized to show real-world clinical practices from the WiNe registry.

Data management

Data sources

Data source(s), other

German WiNe registry

Data sources (types)

Electronic healthcare records (EHR)

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

Unknown