Real World Outcomes of Patients Treated with Vericiguat in German Routine Care (ROVER)

First published: 05/07/2024

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000221

Study ID

1000000221

DARWIN EU® study

No

Study countries

Germany

Study description

This is an observational study in which data already collected from people treated with vericiguat are studied.
In observational studies, only observations are made without participants receiving any advice or any changes to healthcare.

Chronic heart failure with reduced ejection fraction (HFrEF) is a long-term condition that occurs when the heart is weak and cannot pump enough blood to the rest of the body with each heartbeat.
This leads to a reduced supply of oxygen which the body requires to function properly.
The common symptoms include breathlessness, weakness, fatigue, and swelling in the ankles and legs. If left untreated, heart failure can lead to other serious health problems, including damage to other organs, which may result in hospital stays and even death.

Vericiguat works by increasing the activity of an enzyme called soluble guanylate cyclase (sGC), which relaxes the blood vessels and allows more blood to flow through. As a result, the heart is able to pump better.

Vericiguat is available in Germany for the treatment of HFrEF based on the results of a study called VICTORIA. The VICTORIA study showed that vericiguat helps in lowering the chances of death or hospitalization due to heart failure. However, there is limited information available about the use of vericiguat for the treatment of HFrEF under real-world conditions in routine medical care.

The main purpose of this study is to collect information about how well vericiguat works in people with HFrEF who were newly treated with vericiguat. In addition, researchers will collect information about participants’ basic characteristics, including their age, gender, other health conditions they might have, and the medicines they might be taking.

The data will come from 2 German health databases including people who newly started vericiguat treatment between September 2021 and September 2023.

Study status

Ongoing

Research institutions and networks

Institutions

Bayer AG

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Last updated: 01/02/2024

Institution

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

Bayer Clinical Trials BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 03/04/2024

Study start date
Planned: 05/07/2024

Actual: 05/07/2024

Date of final study report
Planned: 31/08/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

BAYER AG

Study protocol

22829_Study Protocol_Redacted_V1.0_2024-07-04.pdf (815.02 KB)

22829 ROVER OS Protocol v1.1 2024-11-20_clean_Redacted.pdf (816.5 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

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

A retrospective single-arm cohort study including new users of vericiguat between SEP 2021 and SEP 2023 will be conducted.

Main study objective:

Describe occurrence of effectiveness outcomes in patients initiating vericiguat

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

VERQUVO

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

VERICIGUAT

Anatomical Therapeutic Chemical (ATC) code

(C01) CARDIAC THERAPY

CARDIAC THERAPY

(C01DX22) vericiguat

vericiguat

Medical condition to be studied

Cardiac failure chronic

Hypotension

Syncope

Additional medical condition(s)

Chronic heart failure with reduced ejection fraction (HFrEF)

Population studied

Short description of the study population

All patients with their first vericiguat prescription since market authorization in September 2021 who are aged 18 years or older will be included in the study.

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

500

Study design details

Setting

The Ingef Database includes the data years between 2014 and 2024 of about 10 Mio. persons. Due to the time delay, especially for outpatient claims data (approx. 6 - 9 months), it can be assumed that the database will be complete up to and including 30st Sep 2023, in accordance with the internal quality controls for data completeness. The WIG2 Database includes the data years between 2014 and 2022 of about 4 Mio. persons.

Outcomes

Primary Outcomes:

- All-cause mortality rates after initiation of vericiguat
- All-cause related hospitalization rates after initiation of vericiguat
- Heart failure related hospitalization rates after initiation of vericiguat

Secondary Outcomes:

- Adherence of vericiguat drug use
- Titration pattern of vericiguat drug use
- Patient persistence of vericiguat drug use
- Socio-demographic characteristics of patients initiating vericiguat at baseline
- Clinical characteristics of patients initiating vericiguat at baseline
- Medication of interest in the 3 months before and after initiation of vericiguat

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Data analysis plan

All analyses will be purely explorative with no a priori defined hypothesis.
Occurrence of the primary composite outcomes will be described as absolute numbers, frequencies, rates per person time as well as in a time to event manner.
Adherence and titration patterns will only be analyzed via absolute numbers and percentages.
The time until discontinuation will additionally be described in a time to event manner.

Factors influencing the occurrence of outcomes will be explored by adequate regression models.

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)

InGef Research Database

Data source(s), other

WIG2 Database

Data sources (types)

Administrative healthcare records (e.g., claims)

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