Mavacamten Real-World Safety: a post-authorisation multi-national, long-term, observational study in patients with obstructive Hypertrophic Cardiomyopathy (oHCM) in the real-world setting in Europe (CV027-013)

First published: 03/01/2024

Last updated: 05/02/2025

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/108179

EU PAS number

EUPAS108178

Study ID

108179

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Sweden
- [ ] United Kingdom

Study description

The aim of this study is to evaluate the risk of clinically important cardiovascular safety-related outcomes among adult patients with symptomatic oHCM receiving mavacamten compared to non-mavacamten oHCM treatment in a real-world setting in Europe.

Study status

Planned

Research institutions and networks

Institutions

Bristol-Myers Squibb (BMS)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Transparency and Disclosure Lead

Study contact

ctt.group@bms.com

Primary lead investigator

Sophie Shen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/06/2024

Study start date

Planned: 31/03/2026

Data analysis start date
Planned: 31/03/2026

Date of final study report
Planned: 31/12/2034

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Main study objective:

The main objective of this study is to estimate the incidence rates of heart failure (HF) associated with exposure to mavacamten and with exposure to non-mavacamten oHCM treatment, among adult patients with symptomatic oHCM and to estimate the risk of HF associated with exposure to mavacamten compared with non-mavacamten oHCM treatment, among adult patients with symptomatic oHCM.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

CAMZYOS

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)

Estimated number of subjects

3648

Study design details

Outcomes

Incidence rate (IR) of Heart Failure (HF) Risk of HF, HF with systolic dysfunction Hospitalisation due to HF Non-fatal myocardial infarction (MI) Non-fatal stroke Arrhythmia Hospitalisation for arrhythmia Atrial fibrillation Atrial flutter Ventricular tachycardia Implanted cardioverter defibrillator therapy 3-point MACE 4-point MACE eMACE Cardiovascular mortality All-cause mortality

Data analysis plan

Data analysis will be performed separately for each registry or database, using statistical packages SAS® Version 9.4 or higher (SAS Institute, Cary, NC, USA) or R (Version 3.5.0 or above), as appropriate.

In the study reports, study results will be presented separately for each registry or database, as appropriate, per data availability.

The complete study results for all registries/databases, including descriptive, comparative, exploratory, and sensitivity analyses, as well as the meta-analysis results (if feasible) will be provided in the final report.

A full description of the analytical approach, data derivations, category definitions, analyses and presentation of the study results will be detailed in the SAP.

The SAP will be finalised prior to the conduct of the study analyses.

Data management

Data sources

Data source(s), other

Register of Hypertrophic Cardiomyopathy (REMY) France, Translational Registry for Cardiomyopathies (TORCH) Germany, Statutory Health Insurance (SHI) Claims Germany, Clinical Practice Research Datalink (CPRD) Aurum United Kingdom, Danish National Health and Socioeconomic registries Denmark

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

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