DARWIN EU® - Prevalence of hypertrophic cardiomyopathy (HCM) and obstructive hypertrophic cardiomyopathy (oHCM) in six European countries

First published: 04/01/2025

Last updated: 14/05/2025

Study Finalised

Administrative details

EU PAS number

EUPAS1000000430

Study ID

1000000430

DARWIN EU® study

Yes

Study countries

- ☐ Croatia
- ☐ Denmark
- ☐ Germany

- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

Study description

Hypertrophic cardiomyopathy (HCM) is an inherited heart disease characterised by an increased wall thickness or mass of the left ventricular wall, with a broad clinical spectrum. HCM is classified into two types based on the presence or absence of left ventricular outflow tract (LVOT) obstruction, a distinction that influences patient management. The obstructive form of HCM (oHCM) is observed in approximately 66% of patients.

The prevalence of HCM was initially estimated at 1 in 500 individuals (0.2%) in a U.S. study. Further U.S. and European studies suggest a lower prevalence of clinically diagnosed HCM. In addition, it has been suggested that some individuals may live normal lifespans undiagnosed because the absent of significant symptoms or major interventions.

Estimating the prevalence of HCM is problematic due to several factors, including the relative rarity of the condition, the high proportion of asymptomatic patients, and diagnostic challenges. Large-scale epidemiological studies on the demographics and morbidity burden of HCM in Europe are scarce.

This study aims to estimate the prevalence of HCM and oHCM across several European countries and different healthcare settings.

Study status

Finalised

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

☐ Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | **Educational Institution** | **ENCePP partner**

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

☐ Belgium
☐ Croatia
☐ Denmark
☐ Estonia
☐ Finland
☐ France
☐ Germany
☐ Greece
☐ Hungary
☐ Italy
☐ Netherlands
☐ Norway
☐ Portugal

☐ Spain

☐ Sweden

☐ United Kingdom

First published: 01/02/2024

Last updated: 30/04/2025

Network

Contact details

Study institution contact

Ilse Schuemie study@darwin-eu.org

Study contact

study@darwin-eu.org

Primary lead investigator

Albert Prats-Uribe

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/10/2024

Actual: 16/10/2024

Study start date

Planned: 11/12/2024

Actual: 11/12/2024

Date of final study report

Planned: 31/03/2025

Actual: 30/04/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P3-C1-018_Prevalence of HCM and oHCM_V3.pdf(722.13 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

The study will consist of a retrospective cohort design including patients with a first diagnosis of HCM or oHCM.

Main study objective:

1. To estimate the annual prevalence of clinically apparent HCM and oHCM in Europe, overall and stratified by age and sex.

2. To characterise patients newly diagnosed with HCM and oHCM in terms of demographics, selected HCM-related clinical measurements, and comorbidities existing before, at the time of, and after a first HCM diagnosis.

3. To describe the frequency of selected HCM-related treatments, including medications, medical devices, and procedures before, at the time of, and after a first HCM diagnosis.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Hypertrophic cardiomyopathy

Additional medical condition(s)

Obstructive Hypertrophic cardiomyopathy

Population studied

Short description of the study population

The study population will include all individuals with a first diagnosis of HCM or oHCM (i.e., index date) identified in the database during the study period and with at least one year of medical history.

Study design details

Setting

This study will be conducted using routinely collected health data from six databases in 6 European countries. All databases were previously mapped to the OMOP CDM.

Data sources:

1. Clinical Practice Research Datalink (CPRD) GOLD, United Kingdom (UK)
2. Danish Data Health Registries (DK-DHR), Denmark
3. InGef Research Database (InGef), Germany
4. Sistema d’Informació per al Desenvolupament de la Investigació en Atenció

Primària (SIDIAP), Spain

5. Croatian National Public Health Information System (NAJS), Croatia

6. Norwegian Linked Health Registry data (NLHR), Norway

Documents

Study report

DARWIN EU_Report_P3-C1-018_Prevalence of HCM and oHCM _V4.pdf(7.31 MB)

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)

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

Clinical Practice Research Datalink (CPRD) GOLD

Danish Health Data Registries

InGef Research Database

The Information System for Research in Primary Care (SIDIAP)

Norwegian Health Registers

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown