DARWIN EU® - Characterising the incidence and presentation of myocarditis and/or pericarditis in Europe

First published: 31/03/2026

Last updated: 31/03/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000967

Study ID

1000000967

DARWIN EU® study

Yes

Study countries

- [ ] Denmark
- [ ] Finland
- [ ] Germany
- [ ] Netherlands

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

Study description

Myocarditis and pericarditis are rare but potentially serious conditions. Evidence on their incidence and presentation remains limited, with reported rates of acute myocarditis ranging from 6.3 to 8.6 per 100,000 individuals and pericarditis ranging from 3 to 32 cases per 100,000 individuals, with higher incidence observed among younger males and older adults. Overlap between myocarditis and pericarditis is frequently observed in clinical practice; Inflammatory myopericardial syndrome (IMPS) has been recently defined to describe the diverse spectrum of the potential overlap between these conditions.

More up-to-date estimates of myocarditis and/or pericarditis incidence and on their representation in terms of prodromes, diagnosis (imaging, biopsy, laboratory tests), management, and outcomes (hospitalisation and mortality) in European Real World Data (RWD) are needed to inform future potential vaccine or drug safety studies.

Study status

Ongoing

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

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ivan Lam

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/01/2026

Actual: 08/01/2026

Study start date

Planned: 23/03/2026

Actual: 23/03/2026

Date of final study report
Planned: 31/07/2026

Sources of funding

- EMA

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:

A population-based cohort and a cohort characterisation studies will be conducted

Main study objective:

1. To estimate the age-standardised incidence rates of myocarditis and/or pericarditis; and the crude incidence rates of myocarditis and/or pericarditis stratified by age and sex, by data source, and by calendar year.
2. To characterise the signs/symptoms, diagnostic procedures (imaging, laboratory measurements, and biopsy), treatment/s, and outcomes (hospitalisation, Intensive Care Unit [ICU] admission, length of hospital stay, mortality) of myocarditis and/or pericarditis as recorded in Real World Data within the DARWIN EU® network during the month before and up to 1 month after diagnosis (of myocarditis and/or pericarditis).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Myocarditis

Pericarditis

Population studied

Short description of the study population

Objective 1 - General population:

The study population will include all individuals observed in each of the participating data sources during the study period who have at least 365 days of data visibility before entering the cohort. The index date of cohort entry will be 1st January 2015 or the date each individual fulfils the eligibility criteria (details in Section 8.6.1.).

Objective 2 - Cohort of people with a diagnosis of myocarditis and/or pericarditis

The study population will include all individuals in each of the participating data sources during the study period who have at least 365 days of data visibility when they have a diagnosis of myocarditis and/or pericarditis and at least 90 days without a record of that same event. The index date will be the date of diagnosis of an eligible myocarditis and/or pericarditis event, i.e., the date of diagnosis/recording of a myocarditis and/or pericarditis after 365 days of data visibility and a 90-day washout (see Section 8.6.1.).

Age groups

- **In utero**
- **Paediatric Population (< 18 years)**
  - Neonate
    - Preterm newborn infants (0 – 27 days)
    - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)

    - Children (2 to < 12 years)
    - Adolescents (12 to < 18 years)
- **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)

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)

Danish Health Data Registries

InGef Research Database

Integrated Primary Care Information (IPCI)

Norwegian Linked Health registry at University of Oslo

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

The Information System for Research in Primary Care (SIDIAP)

The Valencia Health System Integrated Database

Health Impact - Swedish Population Evidence Enabling Data-linkage

Clinical Practice Research Datalink (CPRD) GOLD

Data source(s), other

FinOMOP-THL

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

No