

# mRNA-1273-P910: Clinical course, outcomes and risk factors of myocarditis and pericarditis following administration of Moderna vaccines targeting SARS-CoV-2.

**First published:** 23/05/2023

**Last updated:** 14/07/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS105009

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### Study ID

105010

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### DARWIN EU® study

No

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### Study countries

 Denmark

 Norway

 Spain

## Study description

The overarching goal of this study is to describe the clinical course, outcomes and risk factors for myocarditis and pericarditis associated with Moderna vaccination targeting SARS-CoV-2.

We will investigate the clinical course in terms of morbidity, and identify the relevant prognostic factors using the study objectives.

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## Study status

Finalised

# Research institutions and networks

## Institutions

### Julius Clinical Research

 Netherlands

**First published:** 02/03/2021


**Last updated:** 06/03/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

### Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

 Denmark


**First published:** 20/07/2021

**Last updated:** 08/05/2026

**Institution**

**Educational Institution**

## Drug Safety Research Unit (DSRU)

 United Kingdom

**First published:** 10/11/2021

**Last updated:** 09/01/2026

**Institution**

**Not-for-profit**

**ENCePP partner**

## Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

 Spain

**First published:** 05/10/2012

**Last updated:** 23/05/2025

**Institution**

**Educational Institution**

**Laboratory/Research/Testing facility**

**Not-for-profit**

**ENCePP partner**

## The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

 Spain

**First published:** 01/02/2024

**Last updated:** 31/10/2025

**Institution**

**University of Oslo**

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

## Contact details

### Study institution contact

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**Study contact**

[david.ong@juliusclinical.com](mailto:david.ong@juliusclinical.com)

### Primary lead investigator

David Ong

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Planned: 23/03/2022

Actual: 23/03/2022

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### **Study start date**

Planned: 31/03/2023

Actual: 31/03/2023

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### **Date of final study report**

Planned: 30/06/2025

Actual: 30/06/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Moderna Tx

## Study protocol

[Moderna Myocarditis\\_Nat History Study\\_Protocol\\_version 4.0\\_CLEAN fv\\_Final\\_redacted\\_pdfA\\_archive.pdf](#) (2.06 MB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

EU RMP category 3 (required)

# Other study registration identification numbers and links

mRNA-1273-P910

## Methodological aspects

### Study type

#### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**Study design:**

The study will include 2 distinct designs:

- A case-cohort design to assess risk factors for development of post-vaccine myocarditis and pericarditis;
- A cohort design to characterize the clinical course, outcomes, and risk factors for severe myocarditis and pericarditis.

**Main study objective:**

The primary objectives of this study are:

1. To identify possible risk factors for myocarditis and pericarditis following Moderna vaccination targeting SARS-CoV-2, including demographic characteristics, medical history, and vaccination characteristics.
2. To characterize the clinical course of myocarditis and pericarditis of varying origin, including myocarditis and pericarditis associated with Moderna vaccination targeting SARS-CoV-2, and myocarditis or pericarditis not associated with vaccinations targeting SARS-CoV-2, and to identify prognostic factors in the course of myocarditis and pericarditis.

## Study Design

### **Non-interventional study design**

Case-control

Cohort

Other

## Study drug and medical condition

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

COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED)

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### **Anatomical Therapeutic Chemical (ATC) code**

(J07BN01) covid-19, RNA-based vaccine

covid-19, RNA-based vaccine

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### **Medical condition to be studied**

Myocarditis

Pericarditis

## Population studied

## **Short description of the study population**

For the case-cohort design, individuals with at least one dose of Moderna vaccination targeting SARS-CoV-2 will be used to define a cohort of Moderna vaccination recipients.

Inclusion criteria are at least one year of enrolment in the applicable database prior to the index vaccine dose and without myocarditis events within 6 months prior to receiving a Moderna vaccination targeting SARS-CoV-2.

Cases are those individuals who develop myocarditis or pericarditis any time during the follow-up after Moderna vaccination targeting SARS-CoV-2.

Cases should be able to meet the adjudication criteria according to the Brighton Collaboration Case Definition for possible, probable, or definite myocarditis or pericarditis.

The controls will be sampled from the exposed cohort, such that they align with the distribution of cases based on the month and year of documented Moderna vaccination receipt.

For the cohort design, individuals meeting the criteria of myocarditis or pericarditis, with at least one year of enrolment in the applicable database prior to the index myocarditis or pericarditis event will be included.

Cases of myocarditis and pericarditis will be excluded if these individuals have no record of a Moderna vaccine targeting SARS-CoV-2 but a record of another vaccine targeting SARS-CoV-2 within 30 days prior to the onset of myocarditis or pericarditis.

Within the cohort design, all cases following vaccination are adjudicated according to the Brighton Collaboration Case Definition.

A 1:1 matched sample of the cases not following vaccination matched based on sex and age will also be adjudicated. Only cases that meet the adjudication criteria for possible, probable, or definite myocarditis or pericarditis are included.

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## Age groups

- **Paediatric Population (< 18 years)**

- 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)

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## Estimated number of subjects

6800000

## Study design details

### Setting

This study will include information from multiple databases, utilizing routinely collected health and administrative data of four European countries: Denmark, Norway, Spain (2 databases), and the United Kingdom (UK).

The study databases are representative of the source population in each country.

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### Outcomes

Primary:

1. Risk factors for myocarditis and pericarditis that could potentially include

demographics characteristics, lifestyle factors, medical history and vaccination history

2. Clinical outcomes (death, subsequent cardiovascular events, cardiac hospitalizations) after myocarditis or pericarditis

Secondary:

Risk factors for myocarditis and pericarditis, as well as severe myocarditis and pericarditis

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### **Data analysis plan**

For the case-cohort analysis, all cases of myocarditis and pericarditis and the full control cohort will be described with respect to demographics, lifestyle factors, medical- and vaccination history.

A conditional logistic regression methodology will be applied to identify potential risk factors for development of myocarditis and pericarditis within the Moderna vaccination targeting SARS-CoV-2-exposed population (Primary objective 1).

To identify differences in clinical course (Primary objective 2) and differences in risk factors (Secondary objective 1) for vaccine associated myocarditis/pericarditis and vaccine unrelated myocarditis/pericarditis, cases in the cohort analysis will be compared based on vaccination status.

Outcomes and follow-up care will also be characterized, where feasible.

Standard descriptive statistics will be used to characterise clinical course, outcomes, and long-term outcomes following the initial myocarditis/pericarditis episode.

Cox regression analysis will be utilized to compare the presence of sequelae following myocarditis/pericarditis.

## **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 registries (access/analysis)

Clinical Practice Research Datalink

The Information System for Research in Primary Care (SIDIAP)

Norwegian Health Registers

The Valencia Health System Integrated Database

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### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

[Disease registry](#)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### CDM mapping

Yes

### CDM Mappings

### CDM name

ConcepTION CDM

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**CDM website**

<https://www.imi-conception.eu/>

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**CDM release frequency**

6 months

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## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown