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

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### Administrative details

### Contact details

**Study institution contact** 

David Ong

Study contact

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**Primary lead investigator** 

Ong David

Primary lead investigator

#### **PURI**

https://redirect.ema.europa.eu/resource/105010

**EU PAS number** 

EUPAS105009

Study ID

105010

#### **DARWIN EU® study**

No

#### Study countries

Denmark Netherlands Norway Spain United Kingdom

#### 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 to identify the relevant prognostic factors using the study objectives

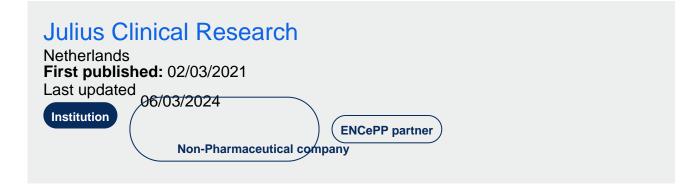
#### Study status

Ongoing

### Research institution and networks

#### Institutions





# Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

First published: 20/07/2021

Last updated

02/04/2024 Institution

> **ENCePP** partner **Educational Institution**

# Drug Safety Research Unit (DSRU)

United Kingdom

First published: 10/11/2021 Last updated 16/02/2024

Institution

**ENCePP** partner

**Educational Institution** 

Not-for-profit

## 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

23/02/2024 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 01/02/2024

Institution

# University of Oslo First published: 01/02/2024

Last updated 01/02/2024

Institution

# FISABIO Spain, University of Oslo Norway

# Study timelines

#### Date when funding contract was signed

Planned: 23/03/2022 Actual: 23/03/2022

#### **Data collection**

Planned: 31/03/2023 Actual: 31/03/2023

#### Date of final study report

Planned: 30/06/2025

# Sources of funding

· Pharmaceutical company and other private sector

### More details on funding

Moderna Tx

# 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

#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness Disease epidemiology

#### Main study objective:

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.

# Study Design

#### Non-interventional study design

Cohort

Other

#### Non-interventional study design, other

Case-series

# Study drug and medical condition

#### Medical condition to be studied

Myocarditis

#### Additional medical condition(s)

Pericarditis

### Population studied

#### Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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**

1

### Study design details

#### **Outcomes**

To identify possible risk factors for myocarditis and pericarditis following Moderna vaccination targeting SARS-CoV-2, including demographic characteristics, medical history, and vaccination characteristics. To characterize the clinical course of myocarditis and pericarditis of varying origin and to identify prognostic factors in the course of myocarditis and pericarditis, To identify whether there are differences in the clinical course and risk factors between myocarditis and pericarditis associated with Moderna vaccination targeting SARS-CoV-2, and myocarditis and pericarditis not associated with vaccinations targeting SARS-CoV-2. For severe cases or cases with sequelae, to identify risk factors for severe myocarditis and pericarditis associated with Moderna vacci

#### Data analysis plan

For the case-cohort analysis, all cases of myocarditis and pericarditis and the full control cohort will be described: demographics, lifestyle factors, medical- and vaccination history. To identify differences in clinical course (Primary objective 2) and differences in risk factors (Secondary objective 1) for vaccine (un)related myocarditis/pericarditis, cases in the cohort analysis will be compared based on vaccination status. Outcomes and follow-up care will also 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**

#### Signed checklist for study protocols

Moderna NatMyo 910 - ENCePPChecklistforStudyProtocols.pdf(222.47 KB)

#### Data sources

#### Data source(s)

Danish registries (access/analysis)
Clinical Practice Research Datalink
The Information System for Research in Primary Care

#### Data source(s), other

VID Spain, Norwegian registries Norway

#### **Data sources (types)**

Administrative data (e.g. claims)
Disease registry
Electronic healthcare records (EHR)

# 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