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: 23/04/2024

Study | Ongoing

Administrative details

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

Julius Clinical Research

Netherlands
First published: 02/03/2021
Last updated
06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

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
02/04/2024

Institution | Educational Institution | ENCePP partner

Drug Safety Research Unit (DSRU)

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

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
23/02/2024

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
01/02/2024

Institution

University of Oslo

First published: 01/02/2024
Last updated
01/02/2024

Institution

FISABIO Spain, University of Oslo Norway

Contact details

Study institution contact

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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
23/03/2022
Actual:
23/03/2022

Study start date
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 (SIDIAP)

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