mRNA-1273-P911: Long-term Outcomes of Myocarditis Following Administration of SPIKEVAX (COVID-19 Vaccine mRNA)

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/107257

EU PAS number

EUPAS107256

Study ID

107257

DARWIN EU® study

No

Study countries

☐ United States

Study description

This is an observational cohort study that combines data collected directly from healthcare providers (HCP) with existing retrospective real-world data as captured in clinical electronic health record (EHR) and administrative claims data. Vaccine exposure and case identification information will be obtained retrospectively from existing real-world data to identify cases of post-vaccine myocarditis (PVM) and ultimately vaccine-associated myocarditis (VAM) for potential study inclusion. Eligible participants will be identified and followed for up to 5 years until the end of the study period or loss to follow-up or death.

Study status

Ongoing

Contact details

Study institution contact

Clinical Trial Disclosure, ModernaTX

Study contact

cttd@modernatx.com

Primary lead investigator

Clinical Trial Disclosure, ModernaTX

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 21/09/2022

Study start date
Actual: 30/04/2022

Data analysis start date
Actual: 31/10/2022

Date of interim report, if expected
Actual: 31/10/2022

Date of final study report
Planned: 31/10/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ModernaTX

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

Main study objective:

The main goal of this study is to characterize presentation, clinical course, and long-term outcomes of myocarditis temporally associated with administration of mRNA-1273 (SPIKEVAX) COVID-19 vaccine.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

SPIKEVAX

Name of medicine, other

Spikevax bivalent

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

1500

Study design details

Outcomes

Outcomes will include major adverse clinical outcomes, structural or functional cardiac abnormalities, and patient-reported outcomes and functional assessments. Required medication or related cardiac procedures during and following hospitalization, along with cardiac or other hospitalization events, and presence and findings from ambulatory monitoring will be described across the follow-up period. Risk factors for adverse long-term outcomes of vaccine-associated myocarditis including demographic factors, lifestyle factors, and medical history.

Data analysis plan

Patients with myocarditis will be described in terms of demographic characteristics, lifestyle factors, and medical history, stratified by and compared across study cohorts. The clinical course of the index myocarditis event will be described for myocarditis cases by exposure status, including analysis of relevant procedures, available data on outcomes, relevant healthcare utilization, and occurrence of additional cardiac events over the follow-up period. Regression models assessing the relative risk of long-term adverse outcomes among vaccine-associated myocarditis (VAM) compared cases

relative to non-vaccine myocarditis (NVM) cases. A predictive modeling approach will be used to identify potential risk factors associated with long-term outcomes, if identified, among vaccine-associated myocarditis cases.

Data management

Data sources

Data source(s), other

Veradigm Network EHR United States, Veradigm Cardiology Registry United States

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Data sources (types)

Administrative healthcare records (e.g., claims)

Other

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