mRNA-1273-P901, Real-World Study of the Effectiveness of Moderna COVID-19 Vaccine

First published: 27/10/2023

Last updated: 14/07/2025

Study Finalised

Administrative details

EU PAS number

EUPAS106670

Study ID

106671

DARWIN EU® study

No

Study countries

United States

Study description

This is an observational cohort study to evaluate real-world vaccine effectiveness and durability of Moderna COVID-19 vaccine among a diverse population at Kaiser Permanente Southern California (KPSC).

Study status

Finalised

Research institutions and networks

Institutions

Kaiser Permanente Southern California (KPSC)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Clinical Trial Disclosure ModernaTX cttd@modernatx.com

Study contact

cttd@modernatx.com

Primary lead investigator

Clinical Trial Disclosure ModernaTX

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 26/01/2021

Study start date
Actual: 18/12/2020

Data analysis start date
Actual: 02/07/2021

Date of final study report
Actual: 28/03/2025

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)

Other study registration identification numbers and links

NCT05933304,
https://clinicaltrials.gov/study/NCT05933304?term=NCT05933304&rank=1

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Main study objective:

The primary objective of this study is to evaluate the vaccine effectiveness (VE) of receipt of Moderna COVID-19 vaccine in preventing SARS-CoV-2 infection and severe COVID-19 disease.
SARS-CoV-2 infection will be defined as a positive antigen test result as well as a positive molecular diagnostic test among symptomatic or asymptomatic participants or a COVID-19 diagnosis code.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ELASOMERAN

IMELASOMERAN

Anatomical Therapeutic Chemical (ATC) code

(J07BN01) covid-19, RNA-based vaccine

covid-19, RNA-based vaccine

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

1.000.000

Study design details

Outcomes

1. Number of Participants With SARS-CoV-2 Infection 2. Number of Participants With Severe COVID-19 Disease

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Data analysis plan

Primary Objectives will be analyzed at interim and final analyses.

Descriptive attributes of vaccinated and unvaccinated cohorts will be presented as absolute no. and %. χ2 test will be used to test for significant differences in the distribution of the categorical covariates among individuals between each of the vaccinated and unvaccinated cohorts at cohort entry.

Continuous variables will be presented as the mean with standard deviation and/or median with interquartile ranges, with p-values for the two-sample test or Wilcoxon rank-sum test, as appropriate.

Absolute standardized differences will be calculated to assess the balance of covariates.

Overall incidence rates of SARS-CoV-2 infection and of severe COVID-19 for the vaccinated and unvaccinated cohorts will be calculated by dividing the no. of incident events by the total no. of person-yrs. Vaccine Effectiveness will be estimated using Cox Proportional Hazards and Logistic Regression methods where appropriate.

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 sources (types)

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