Epidemiological study of COVID-19 among hospital employees: extension study of the ‘CovidPreventMainz’ (CPM) study (CPMprevac)

First published: 11/09/2020

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS37174

Study ID

48688

DARWIN EU® study

No

Study countries

Germany

Study description

Given the rapidly changing situation and the urgent need to accelerate the licensing of efficacious candidate vaccines against SARS-CoV-2 infection, this study aims to provide information on the evolution of the epidemiology of COVID-19 in support of a vaccine field efficacy trial. This study aims to describe the epidemiology of COVID-19 in a collective of university hospital employees in order to assess the feasibility of performing a field efficacy trial of CureVac's investigational SARS-CoV-2-mRNA vaccine (CVnCoV).

Study status

Ongoing

Research institutions and networks

Institutions

Universitätsmedizin der Johannes Gutenberg

First published: 01/02/2024

Last updated: 01/02/2024

Institution

UM Mainz

Contact details

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Study contact

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Primary lead investigator

Stephan Gehring

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 28/08/2020

Study start date

Actual: 31/08/2020

Data analysis start date

Planned: 01/10/2020

Actual: 16/10/2020

Date of interim report, if expected

Planned: 05/10/2020

Actual: 04/11/2020

Date of final study report

Planned: 15/10/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

CureVac AG

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

This study aims to describe the epidemiology of COVID-19 in a collective of a German university hospital employees (including human medicine and dentistry

students with contact to patients) in order to support the initiation, as well as enhance the analytical power, of a field efficacy trial of Curevac’s investigational SARS-CoV-2-mRNA vaccine (CVnCoV).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

SARS-CoV-2 test

SARS-CoV-2 antibody test

Additional medical condition(s)

COVID-19 cell-mediated immune responses.,COVID-19 clinical disease.

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Estimated number of subjects

3500

Study design details

Outcomes

• Seroconversion due to SARS-CoV-2 infection measured by SARS-CoV-2-specific antibodies in serum samples. • Virologically-confirmed symptomatic COVID-19 clinical disease Case definition 1: FDA, • Virologically-confirmed symptomatic COVID-19 clinical disease Case definition 2: CEPI • Severity of COVID-19 clinical disease Case definition 1: FDA Case definition 2: CEPI • Cell-mediated immune responses in persons with proven SARS-CoV-2 infection • Clinical presentation of suspected COVID-19 cases • Prevalence of asymptomatic SARS-CoV-2 infection

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Data analysis plan

The study population will be described using frequency tables and proportions. The prevalence of seroconversions will be calculated absolute, and analysed stratified by age group, sex and other risk factors. Incidence rates (IRs) will be calculated for confirmed COVID-19 disease, using the two described case definitions. Disease severity will be described, using two case definitions.

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)

Other

Data sources (types), other

Health care workers at University Hospital.

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