

EHDS2 Pilot Use Case: Natural history of coagulopathy in COVID-19 patients and persons vaccinated against SARS-CoV-2 during the Omicron period.

First published: 24/10/2023

Last updated: 24/10/2023

Study

Ongoing

Administrative details

EU PAS number

EUPAS107315

Study ID

107316

DARWIN EU® study

No

Study countries

☐ Croatia

☐ Denmark

☐ Estonia

- ☐ Finland
 - ☐ France
 - ☐ Netherlands
 - ☐ Spain
 - ☐ United Kingdom
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Study description

HealthData@EU is the European Health Data Space (EHDS) Pilot project that aims to investigate and establish an infrastructure and data ecosystem for the secondary use of health data for research, innovation and better policy making in Europe. The proposed study is one of the five use cases selected to test and inform HealthData@EU frameworks. The aim of the study is to contextualise the risk of venous and arterial thromboembolic events associated with COVID-19, during the period when Omicron dominant, in light of past COVID-19 infection and SARS-CoV-2 vaccination. This will be performed in a federated manner through multiple international databases to inform the HealthData@EU project.

Study status

Ongoing

Research institutions and networks

Institutions

[European Medicines Agency \(EMA\)](#)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Pharmaco- and Device epidemiology, University of Oxford

☐ United Kingdom

First published: 12/09/2023

Last updated: 11/07/2024

Institution

Educational Institution

ENCePP partner

IQVIA

☐ United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution

Non-Pharmaceutical company

ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Daniel Morales

Study timelines

Date when funding contract was signed

Planned: 30/09/2022

Actual: 30/09/2022

Study start date

Planned: 01/05/2023

Actual: 01/05/2023

Date of final study report

Planned: 24/10/2023

Sources of funding

- EU institutional research programme

More details on funding

EU Commission

Study protocol

[EHDS-Coagulopathy-protocol_EHDS2.pdf](#)(356.8 KB)

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

Main study objective:

The aim of the study is to contextualise the risk of venous and arterial thromboembolic events associated with COVID-19, during the Omicron period when Omicron, and SARS-CoV-2 vaccination.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07BN) Covid-19 vaccines

Covid-19 vaccines

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

30000000

Study design details

Outcomes

Venous and arterial thromboembolic events, Worsening COVID-19 disease progression

Data analysis plan

Descriptive analysis Cause-specific Cox models to examine risk factors associated with thromboembolic events in patients with COVID-19 Crude and standardized incidence rate ratios (SIRs) for thromboembolic events in each

cohort of interest.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

Danish registries (access/analysis)

Data source(s), other

IQVIA Germany Germany, Information System of the Republic of Croatia

Croatia, Système National des Données de Santé France, Estonian Biobank
Estonia

Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

[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