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

PURI
https://redirect.ema.europa.eu/resource/107316

EU PAS number
EUPAS107315

Study ID
107316

DARWIN EU® study
No

Study countries
Croatia
Denmark
Estonia
Finland
France
Netherlands
Spain
United Kingdom

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 institution 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 (Northern Ireland)
First published: 12/09/2023
Last updated 12/09/2023
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
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Primary lead investigator

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

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
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 Donnés de Santé France, Estonian Biobank Estonia

Data sources (types)
Administrative data (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