Cohort monitoring of Adverse Events of Special Interest and COVID-19 diagnoses prior to and after COVID-19 vaccination (ECVM)

First published: 01/04/2021

Last updated: 01/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50430

EU PAS number

EUPAS40404

Study ID

50430

DARWIN EU® study

No

Study countries

- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom (Northern Ireland)

Study description

This study will monitor AESI prior and following COVID-19 vaccination, with the purpose to estimate the incidence rates and pick up signals. This study will be conducted with funding from the EMA and in 4 data sources that have access to COVID-19 vaccine data and are able to rapidly update their data

Study status

Finalised

Research institutions and networks

Institutions

University Medical Center Utrecht (UMCU)

- [ ] Netherlands

First published: 24/11/2021

Last updated: 22/02/2024

Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility** | **ENCePP partner**

Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

Netherlands

First published: 01/03/2010

Last updated: 23/05/2024

Institution | Educational Institution | ENCePP partner

University Medical Center Utrecht (UMCU)

Netherlands

First published: 24/11/2021

Last updated: 22/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

First published: 07/01/2022

Last updated: 24/07/2024

Institution | Laboratory/Research/Testing facility | ENCePP partner

Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency for Medicines and Medical Devices, AEMPS)

☐ Spain

First published: 01/02/2024

Last updated: 04/09/2024

Institution | EU Institution/Body/Agency | Not-for-profit | Regulatory Authority | ENCePP partner

Multiple centres: 6 centres are involved in the study

Networks

Vaccine monitoring Collaboration for Europe (VAC4EU)

☐ Belgium

☐ Denmark

☐ Finland

☐ France

- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

First published: 22/09/2020

Last updated: 22/09/2020

Network | ENCePP partner

EU Pharmacoepidemiology and Pharmacovigilance (PE&PV) Research Network

- [ ] Netherlands

First published: 01/02/2024

Last updated: 26/11/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Miriam Sturkenboom

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/12/2020

Study start date

Planned: 15/02/2021

Actual: 15/02/2021

Data analysis start date

Planned: 30/03/2021

Date of final study report

Planned: 30/11/2021

Actual: 08/06/2022

Sources of funding

- EMA

Study protocol

Early-COVID-Vaccine-Monitorprotocol_EHRdatav0.2_20210331.pdf(663.74 KB)

Early-COVID-Vaccine-Monitorprotocol_EHRdatav1.5 CLEAN.pdf(1.36 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To monitor the use and effects of COVID-19 vaccines

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective, multi-database, dynamic study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07BC20) combinations

combinations

Medical condition to be studied

Coagulopathy

Additional medical condition(s)

Cardiovascular, Immunological

Population studied

Short description of the study population

The study involved participants from 4 European countries, including Italy, the Netherlands, Spain, and the United Kingdom, spanning from January 1st, 2020 to October 31st, 2021. The source population consisted of approximately 36 million individuals, with 7 million in the Netherlands, 8 million in Spain, 3.5 million in Italy, and 16 million in the UK.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

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)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

5000000

Study design details

Data analysis plan

Risk estimation

Documents

Study publications

Sturkenboom M, Messina D, Paoletti O, de Burgos-Gonzalez A, García-Poza P, Huer…

Sturkenboom M. Cohort monitoring of Adverse Events of Special Interest and COVI…

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

PHARMO Data Network

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

ARS Toscana

Data source(s), other

CPRD, PHARMO Data Network, BIFAP, ARS

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