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





Administrative details

EU PAS number	
EUPAS40404	
Chudu ID	
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



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		
University Medical Center Utrecht (UMCII)		
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		
The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)		
(PHARMO Institute)		
(PHARMO Institute) Netherlands		
(PHARMO Institute) Netherlands First published: 07/01/2022		
(PHARMO Institute) Netherlands First published: 07/01/2022 Last updated: 24/07/2024		

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			
ENCePP partner			
Multiple centres: 6 centres are involved in the study			
Networks			
Vaccine monitoring Collaboration for Europe (VAC4EU) Belgium Denmark Finland			
France			

Germany

Netherlands

___ Italy

Norway
Spain
United Kingdom
First published: 22/09/2020
Last updated: 22/09/2020
Network Outdated ENCePP partner

EU Pharmacoepidemiology and Pharmacovigilance (PE&PV) Research Network

Netherlands

First published: 01/02/2024

Last updated: 24/09/2025

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?
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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

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 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	map	ping
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No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No