Background rates of Adverse Events of Special Interest for monitoring COVID-19 vaccines (ACCESS-BGR)

First published: 22/09/2020

Last updated: 01/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS37273

Study ID

50442

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Italy

☐ Netherlands

☐ Spain

☐ United Kingdom

Study description

This study aims to generate background rates of adverse events of special interest for monitoring of COVID-19 vaccines, in 10 healthcare databases in 7 European countries

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

Netherlands Pharmacovigilance Centre Lareb

Netherlands

First published: 05/02/2010

Last updated: 19/07/2016

Institution | Not-for-profit | ENCePP partner

Fundació Institut Català de Farmacologia (FICF)

Spain

First published: 29/03/2010

Last updated: 17/09/2019

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | 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

Department of Biomedical and Dental Sciences and Morphofunctional Imaging, University of Messina

Italy

First published: 29/11/2021

Last updated: 20/08/2024

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

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/02/2023

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | 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: 12 centres are involved in the study

Networks

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

Miriam Sturkenboom m.c.j.sturkenboom@umcutrecht.nl

Study contact

m.c.j.sturkenboom@umcutrecht.nl

Primary lead investigator

Miriam Sturkenboom

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/05/2020

Actual: 19/05/2020

Study start date

Planned: 01/10/2020

Actual: 01/10/2020

Data analysis start date

Planned: 16/11/2020

Date of interim report, if expected

Planned: 15/12/2020

Date of final study report

Planned: 29/01/2021

Actual: 30/06/2021

Sources of funding

- EMA

Study protocol

ACCESS_BGRprotocolSept222020.pdf(1.31 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

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

To generate background incidence rates of adverse events of special interest (AESI) that may be used to monitor benefit-risk profile of upcoming 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

Medical condition to be studied

Narcolepsy

Acute aseptic arthritis

Thrombocytopenia

Microangiopathy

Cardiac failure

Arrhythmia

Myocarditis

Embolism

Haemorrhage

Liver injury

Encephalitis

Erythema multiforme

Pernio-like erythema

Anosmia

Anaphylactic reaction

COVID-19

Stillbirth

Death

Additional medical condition(s)

Stress cardiomyopatly, Generalized convulsion, Multisystem Inflammatory disease, Preeclampsia, Major congenital anomaly

Population studied

Short description of the study population

The study population included individuals registered in health insurance data (BIPS, SNDS), hospitalisation record linkage data (PHARMO, Danish registries, FISABIO, SIDIAP, ARS) or data from general practitioners (CPRD, PEDIANET, BIFAP) from 2017 to 2020, including the period of SARS-CoV-2 circulation in Europe until the date of last data availability for each data source.

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

130

Study design details

Outcomes

Incidence rates of adverse events of special interest (AESI) and pregnancy outcomes in the general population by calendar year and data source over the period 2017 to 2020, Weekly and monthly incidence rates of COVID-19 (overall and by severity level) in 2020 by data source, Monthly incidence rates of multisystem inflammatory syndrome in children (MIS-C) in 2020 by data source.

Incidence rates of AESI by calendar month, year, sex, age group, and data source over the period 2017 to 2020, Incidence rates of multisystem MIS-C in 2020 by month, sex, age group, and data source, Prevalence of high-risk medical conditions for developing severe COVID-19 by year and data source, incidence rates of AESI in the at-risk population by year, sex, age group, and data source

Data analysis plan

Incidence rates (and 95%CI) of AESI and pregnancy outcomes by calendar year will be calculated by dividing the number of incident (new) cases by the total person-time at risk. Prevalence rates (and 95%CI) of at-risk medical conditions for developing severe COVID-19 by calendar year will be calculated by dividing the number of existing cases in a year by the average of the total number of persons recorded monthly. Incidence rates (and 95%CI) of AESI among at-risk populations will also be computed. Sensitivity analyses will be conducted according to the time prior to SARS-CoV2 circulation and during SARS-CoV2 circulation period to investigate the impact of circulating virus on incidence rates.

Documents

Study results

ACCESS Final Report Zenodo link.pdf(50.71 KB)

Study publications

Willame C, Dodd C, Durán CE, Elbers R, Gini R, Bartolini C, Paoletti O, Wang L,...

Willame C, Dodd C, Durán CE, Elbers RJ, Gini R, Bartolini C, Paoletti O, Wang L...

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

Danish registries (access/analysis)

The Information System for Research in Primary Care (SIDIAP)

PHARMO Data Network

German Pharmacoepidemiological Research Database

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

ARS Toscana

Pedianet network

Data source(s), other

CPRD/HES, Danish Registries (access/analysis), SIDIAP, PHARMO Data Network, BIFAP, ARS, Pedianet

---

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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