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

First published: 22/09/2020
Last updated: 23/04/2024

Study Finalised

Administrative details

Contact details

Study institution contact
Miriam Sturkenboom
Study contact

m.c.j.sturkenboom@umcutrecht.nl
Primary lead investigator
Miriam Sturkenboom
Primary lead investigator

PURI
https://redirect.ema.europa.eu/resource/50442

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 institution 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 16/04/2024

Institution
Educational Institution
ENCePP partner

Netherlands Pharmacovigilance Centre Lareb

Netherlands
First published: 05/02/2010
Last updated 19/07/2016

Institution | ENCePP partner | Not-for-profit

Pharmacoepidemiology and Pharmacovigilance department, Spanish Agency of medicines and medical devices (AEMPS)

Spain
First published: 31/07/2014
Last updated 18/10/2018

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

Fundació Institut Català de Farmacologia (FICF)

Spain
First published: 29/03/2010
Last updated 17/09/2019

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

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

Italy
First published: 29/11/2021
Last updated 01/12/2021

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

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

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 12/03/2024

Network

Study timelines

Date when funding contract was signed
Planned:
19/05/2020
Actual:
19/05/2020

Data collection
Planned:
01/10/2020
Actual:
01/10/2020

Start date of data analysis
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 topic:
Disease /health condition

Study type:
Non-interventional study

Scope of the study:
Disease epidemiology

Data collection methods:
Secondary data collection

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

Results tables
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

Data sources

Data source(s)
Clinical Practice Research Datalink
Danish registries (access/analysis)
The Information System for Research in Primary Care
PHARMO Data Network
German Pharmacoepidemiological Research Database

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 data (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