Cohort Event Monitoring of safety of COVID-19 vaccines (Early-) Covid-Vaccine-Monitor (Covid-Vaccine-Monitor ECVM CVM)

First published: 18/03/2021

Last updated: 23/05/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49318

EU PAS number

EUPAS39798

Study ID

49318

DARWIN EU® study

No

Study countries

☐ Belgium

- [ ] Croatia
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Luxembourg
- [ ] Netherlands
- [ ] United Kingdom

Study description

Primary aim: to generate incidence rates of patient-reported ADRs of COVID-19 vaccine brand in near real-time. Secondary aim: to describe differences in ADRs incidence rates between different vaccine batches used across the participating countries. In different countries, on the national level, data will be prospectively collected in near real-time, directly from a cohort of vaccine recipients. The common core data from different countries will be pooled and analysed at the European level. Vaccine recipients will be asked to fill in questionnaires at baseline, 1, 3, 5 and 8 weeks and 3 and 6 months after vaccination (from the first dose). The exact timing of the sending of the third questionnaire will depend on the vaccination interval between two doses. Safety data will be directly reported by vaccine recipients in their local language using the Lareb Intensive Monitoring (LIM) web app, which has been built specifically for patient-reported outcomes. Reported data from European countries using this LIM app can be stored in a dedicated central database. Data can also be collected nationally with non-LIM intensive monitoring tools/apps and countries can store and code data locally and share at regular intervals. ADR incidence rates within the vaccinated cohort will be reported cumulatively every month, overall and for the different vaccine brands, gender, age group, and countries. The protocol has been developed by the EU PE&PV research network as a deliverable of the framework contract No EMA/2018/28/PE with the European Medicines Agency.

Study status

Finalised

Research institutions and networks

Institutions

Netherlands Pharmacovigilance Centre Lareb

Netherlands

First published: 05/02/2010

Last updated: 19/07/2016

Institution | Not-for-profit | ENCePP partner

Netherlands Pharmacovigilance Centre Lareb

Netherlands

First published: 05/02/2010

Last updated: 19/07/2016

Institution | Not-for-profit | ENCePP partner

Drug Safety Research Unit (DSRU)

United Kingdom

First published: 10/11/2021

Last updated: 16/02/2024

Institution | Not-for-profit | 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

Federal Agency for Medicines and Health Products (FAHMP) Belgium, University of Verona Italy, Paul Ehrlich Institute (PEI) Germany, HALMED Croatia

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

Agnes Kant

Study contact

a.kant@lareb.nl

Primary lead investigator

Agnes Kant

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/12/2020

Actual: 11/12/2020

Study start date

Planned: 01/02/2021

Actual: 15/12/2020

Date of interim report, if expected

Planned: 06/04/2022

Actual: 08/04/2022

Date of final study report

Planned: 06/06/2023

Actual: 08/05/2023

Sources of funding

- EMA

Study protocol

CVM_WP2_Protocol_v2.1_20210825.pdf(1.33 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:

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

to generate incidence rates of patient-reported ADRs of COVID-19 vaccine brand in near real time.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective cohort study, Prescription event monitoring

Population studied

Short description of the study population

The study population included recipients of covid-19 vaccines identified through six European countries: The Netherlands, Italy, France, United Kingdom, Germany, and Croatia.

Inclusion criteria:

Participants to be included should be vaccinated in one of the participating countries in the period February onwards until the minimal amount of inclusions has been reached. The vaccine recipient or their proxy should:
• register for the study prior to (the first) vaccination or no longer than 2 days after COVID-19 vaccination;
• be able to understand the language of the survey (which should at least be translated into the local official languages);
• be able to register and participate by e-mail;
• provide informed consent (which should at least be translated into the local official languages)

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

57000

Study design details

Outcomes

Participants will be asked to report adverse reactions after vaccination at multiple follow-up time points. These adverse reactions are known to frequently occur. In addition, it will be asked whether any other adverse reactions occurred (open question/unsolicited).

Data analysis plan

A description of the population at inclusion will be made by participating parties, comprising of the number of patients included in the cohort, distribution of gender, age categories (to be defined), country and additional core data. A dedicated cumulative structured overview of numbers and incidence rate of all adverse reactions per vaccine will be provided every month, overall, and also stratified by vaccine brand, country, gender and age group. For each ADR, incidence rate with its 95% confidence interval (CI) will be reported by COVID-19 vaccine brand and dose. Monthly overviews will be made available on a national level for national competent authorities but also made available to the partners.

Documents

Study results

EUPAS39798-105810.pdf(567.7 KB)

EUPAS39798-106508.pdf(623.95 KB)

Study publications

Raethke M, van Hunsel F, Thurin NH, Dureau-Pournin C, Mentzer D, Kovačić B, Mir…

Luxi, N, Raethke, M, Ruijs, L, Schmikli, S, Riefolo, F, Trifiro, G, & Sturkenbo…

Raethke, Monika, Ruijs, Loes, Schmitz, Jasper, Perez-Gutthan, Susana, Droz, Céc…

Luxi Nicoletta, Riefolo Fabio, Raethke Monika, van Hunsel Florence, Sturkenboom…

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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