Cohort Event Monitoring of safety of COVID-19 vaccines in special populations (pregnant and lactating women, children and adolescents, immunocompromised, people with history of allergy, people with prior SARS-CoV-2 infection) (Covid-Vaccine-Monitor CVM)

First published: 23/08/2021
Last updated: 23/04/2024

Study | Finalised

Administrative details

Contact details

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PURI
https://redirect.ema.europa.eu/resource/47756

EU PAS number
EUPAS42504

Study ID
47756

DARWIN EU® study
No

Study countries
Ireland
Italy
Netherlands
Portugal
Romania
Slovakia
Spain
Switzerland

Study description
Primary aim: To generate and compare incidence rates of patient-reported adverse reactions of different COVID-19 vaccines in pregnant and lactating women, children and adolescents, immunocompromised, people with history of allergy and people with prior SARS-CoV-2 infection.
Secondary aim: Within each special cohort of vaccinees to identify potential predictors of the most frequently reported adverse reactions related to different COVID-19 vaccines.
The study is a prospective cohort study in special populations (pregnant and lactating women, children and adolescents, immunocompromised, people with history of allergy and people with prior SARS-CoV-2 infection). In different countries, on the national level, data will be prospectively collected, directly from a cohort of vaccine recipients. The common core data from different countries will be pooled, stratified by special cohort and analysed at the European level. The?study?is set up as a cohort monitoring for?a?duration of up until 6 months from the first dose vaccination date (except for pregnant women who will be followed up until 1.5 month after the pregnancy end).? Vaccine recipients should be asked to fill in questionnaires at baseline, and 1 and 3 weeks after the first dose (and eventually the second dose), and 3 and 6 months after first dose vaccination. As regards pregnant women a specific “End of Pregnancy” questionnaire will be additionally sent within 1.5 months from the estimated delivery to collect information on outcomes related to pregnancy and new-born. Safety data can be directly reported by vaccine recipients in their local language using the Lareb Intensive Monitoring (LIM) web app or the ResearchOnline web app. Collected data can be stored in dedicated central databases. For each special cohort, adverse reaction incidence rates will be reported overall and stratified and compared across different vaccine brands, gender, age groups, and countries.

Study status
Finalised

Research institution and networks

Institutions

Unit of Clinical Psychopharmacology and Drug Epidemiology, University of Verona

Italy
First published: 17/07/2012
Last updated 03/07/2014

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

Netherlands Pharmacovigilance Centre Lareb

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

Institution
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

Pharmacology Unit - Veneto Pharmacovigilance Centre (Pharmacol UNIVR), University Hospital Verona

Italy
First published: 25/10/2022
Last updated 26/10/2022

Institution

Educational Institution

Hospital/Clinic/Other health care facility

ENCePP partner

- CLPP Vaccines Network, Portugal
- University of Medicine and Pharmacy ‘Iuliu Hatieganu’ Cluj-Napoca, Romania
- Medical faculty of Pavol Jozef Safarik University SLOVACRIN), Slovakia
- University of Verona, Italy
- University of Bern, Switzerland
- Rotunda Hospital Dublin, Ireland
- ilmiovaccinoCOVID19 collaborating group, Italy

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:
06/04/2021
Actual:
06/04/2021

Data collection
Planned:

07/07/2021
Actual:
07/07/2021

Start date of data analysis
Actual:
30/09/2021

Date of interim report, if expected
Planned:
06/04/2022
Actual:
08/04/2022

Date of final study report
Planned:
06/04/2023
Actual:
08/05/2023

Sources of funding

- EMA

Study protocol

CVM_WP1_Protocol_v2.0_20210714_final.pdf(793.44 KB)

CVM_WP1_Protocol_v2.1_20210729.pdf(1.42 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:
Secondary data collection

Study design:
Prospective cohort study in special populations (pregnant and lactating women, children and adolescents, immunocompromised, people with history of allergy and people with prior SARS-CoV-2 infection).

Main study objective:
To generate and compare incidence rates of patient-reported adverse reactions of different COVID-19 vaccines across the participating countries in pregnant and lactating women, children and adolescents, immunocompromised, people with history of allergy and people with prior SARS-CoV-2 infection.

Study Design

Non-interventional study design
Cohort
Other

Non-interventional study design, other
Prospective study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
100000096568
combinations

Medical condition to be studied
Pregnancy
COVID-19

Population studied

Short description of the study population
The study population comprised of pregnant and lactating women, children and adolescents, immunocompromised, people with history of allergy and people with prior SARS-CoV-2 infection who received COVID-19 vaccines for period of February 2021 to August 2022.

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)
Adult and elderly population (>18 years)
Adults (18 to < 65 years)
Adults (18 to < 46 years)
Adults (46 to < 65 years)
Elderly (? 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
60000

Study design details

Data analysis plan
Risk estimation: for each special cohort, a dedicated cumulative structured overview of numbers and incidence of all adverse reactions per vaccine will be provided, overall, and also stratified by vaccine brand, country, gender, and age group. For each adverse reaction, cumulative incidence with its 95% confidence interval (CI) will be reported by COVID-19 vaccine brand and dose.

Documents

Results tables
EUPAS42504-105818.pdf(567.7 KB)

EUPAS42504-106484.pdf(623.95 KB)

Study publications
Ahmadizar F, Luxi N, Raethke M, Schmikli S, Riefolo F, Saraswati PW, Bucsa C, O…
Luxi, N, Raethke, M, Ruijs, L, Schmikli, S, Riefolo, F, Trifiro, G, & Sturkenbo…
Luxi Nicoletta, Riefolo Fabio, Raethke Monika, van Hunsel Florence, Sturkenboom…
Francesco Ciccimarra et al. (2024). Safety Monitoring of COVID-19 Vaccines in P…

Data management

Data sources

Data source(s), other
Safety data can be directly reported by vaccine recipients in their local language using the Lareb Intensive Monitoring (LIM) web app or the ResearchOnline web app, which have been both built specifically for patient-reported outcomes using exactly the same structure. As regards pregnancy monitoring, only ResearchOnline will be used as collecting additionally information on pregnancy. Collected data from European countries using LIM/ResearchOnline web app can be stored in dedicated central databases.

Data sources (types)
Administrative data (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