

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: 13/12/2024

Study

Finalised

Administrative details

EU PAS number

EUPAS42504

Study ID

47756

DARWIN EU® study

No

Study countries

- ☐ Ireland
 - ☐ Italy
 - ☐ Netherlands
 - ☐ Portugal
 - ☐ Romania
 - ☐ Slovakia
 - ☐ Spain
 - ☐ Switzerland
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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 institutions 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: 13/03/2025

Institution

Educational Institution

Hospital/Clinic/Other health care facility

ENCePP partner

Teamit Institute

☐ Spain

First published: 12/03/2024

Last updated: 12/03/2024

Institution

Other

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: 26/11/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Gianluca Trifirò

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/04/2021

Actual: 06/04/2021

Study start date

Planned: 07/07/2021

Actual: 07/07/2021

Data analysis start date

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 use of data

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

(J07BC20) combinations

combinations

Medical condition to be studied

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 (\geq 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

Study results

[EUPAS42504-105818.pdf](#)(567.7 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...](#)

[What is the Safety of COVID-19 Vaccines in Immunocompromised Patients? Results ...](#)

[Safety of COVID-19 Vaccines among People with History of Allergy: A European Ac...](#)

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 healthcare records \(e.g., claims\)](#)

[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