Programme d’évaluation de la vaccination COVID-19 : Risque d’effets indésirables d’intérêt des différents vaccins et comparaison du bénéfice-risque des vaccins (EVACOV-RISC)

First published: 08/03/2023
Last updated: 23/07/2024

Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/104059

EU PAS number
EUPAS103839

Study ID
104059

DARWIN EU® study
No

Study countries
France

Study status
Planned

Research institution and networks

Institutions

University of Bordeaux

France
First published: 01/02/2024
Last updated
01/02/2024

Institution

Educational Institution

Contact details

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Primary lead investigator
Nicolas Thurin

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
17/10/2022

Study start date
Planned:
31/12/2022

Date of final study report
Planned:
30/09/2026

Sources of funding

- Other

More details on funding

Ministère de l'Enseignement supérieur, de la Recherche et de l'Innovation via l’ANRS-Maladies Infectieuses Emergentes

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness
Disease epidemiology
Drug utilisation
Effectiveness study (incl. comparative)

Main study objective:
The first objective is to evaluate the incidence rate of each adverse event of special interest (AESI) following the introduction of various anti-COVID-19 vaccines in the French population compared to the baseline rates estimated just before their introduction. The second one is to compare the risk of each AESI between vaccinated and non-vaccinated persons, and between the different vaccines.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(J07BX) Other viral vaccines

Medical condition to be studied
COVID-19 immunisation

Population studied

Age groups
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)

Estimated number of subjects
6700000

Study design details

Outcomes
The primary outcomes are the AESIs included in the list set up in collaboration with the EMA.

Data analysis plan
For each year (2021, 2022, 2023) in the SNDS, 3 cohorts will be defined: one on a random sample of 10% of the French population, one on all patients with an AESI, and one on all pregnant women. For the first objective, the incidence rate of each AESI will be compared before (2017-2020) and after the introduction of vaccines. Interrupted time series and time-to-onset analyses related to the date of vaccination should complete these elements. For the second objective, a comparative approach relying on propensity score matching will be set up to assess AESI relative risks between vaccinated and non-vaccinated subjects. A self-controlled risk interval design will also be implemented for all suitable AESIs.

Data management

Data sources

Data source(s), other
SNIIRAMSNDS France

Data sources (types)
Administrative data (e.g. claims)

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