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)

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Study Planned

Administrative details

EU PAS number

EUPAS103839

Study ID

104059

DARWIN EU® study

No

Study countries

☐ France

Study status

Planned

Research institutions and networks

Institutions

University of Bordeaux

France

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Institution | Educational Institution

Contact details

Study institution contact

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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

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 healthcare records (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