Risk of thromboembolic events and thrombocytopenia after vaccination against COVID-19 (Thrombosis risk COVID-19 vaccination)

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Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/49096

EU PAS number
EUPAS49085

Study ID
49096

DARWIN EU® study
No

Study countries
Spain

Study description
Rationale and background: In March 2021, cases of thrombotic events associated with thrombocytopenia began to appear after the administration of AstraZeneca's COVID-19 vaccine. Although the risk following administration of AstraZeneca and Janssen vaccines for these thrombotic or embolic disorders with and without thrombocytopenia, as well as for thrombocytopenia without associated thromboembolism, has been established, it has not yet been fully characterised and quantified. Objectives: To quantify the association between the occurrence of thromboembolic events and thrombocytopenia, separately and

thromboembolism together with thrombocytopenia and the administration of COVID-19 vaccines. Data source: BIFAP (Base de datos para la Investigación Farmacoepidemiológica en el Ámbito Público). Study design: A self-controlled case series (SCCS) design with pre- and post-vaccine control intervals as the main analysis. Also, exploratory analyses will be conducted: firstly, using an SCCS design with a post-vaccine control interval only, and secondly, using a self-controlled risk interval (SCRI) design. The study period will be from September 1st, 2020, until death, patient exit from the database, or end of study. Population: All individuals aged ?5 years, registered with their primary care physician for at least 365 days, who have received one of the following COVID-19 vaccines: AstraZeneca, Pfizer, Moderna, or Janssen and for whom any of the defined outcomes of interest have been identified. Events of interest: Venous thromboembolism, arterial thromboembolism, and thrombocytopenia, as well as concomitance of thromboembolism with thrombocytopenia. Data analysis: Description of the study population characteristics. For all study designs, we will compare the event rates in the post-vaccination risk period with the control periods using conditional Poisson regression, by type of vaccine.

Study status
Planned

Research institution and networks

Institutions

Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency for Medicines and Medical Devices, AEMPS)

Spain
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Institution
EU Institution/Body/Agency
Not-for-profit
Regulatory Authority

Contact details

Study institution contact
Mar Martín-Pérez
Study contact

mmmartinp@aemps.es

Primary lead investigator
Patricia García Poza
Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
14/01/2022

Study start date
Planned:
24/10/2022

Date of final study report
Planned:
15/03/2023

Sources of funding

- Other

More details on funding

AEMP's own resources. No funding has been received.

Study protocol

Protocol_Risk thrombosis after COVID19 vaccines_vs2_sep2022.pdf(514.74 KB)

Regulatory

Was the study required by a regulatory body?
No

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

Other study registration identification numbers and links

BIFAP Scientific Committee registration number: 13_2021, and Comité de Ética de La Investigación con Medicamentos del Hospital Universitario de la Princesa (i.e. Ethics Committee) approval: 21-02-22, acta CEIm 04/22.

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness

Main study objective:
To quantify the association between the occurrence of thromboembolic events and thrombocytopenia, separately, as well as thromboembolism together with thrombocytopenia, and the administration of COVID-19 vaccines within pre-specified risk periods after vaccination, stratified by vaccine, age, sex and risk factor groups.

Study Design

Non-interventional study design
Other

Non-interventional study design, other
Self-controlled case series

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(J07BX03) covid-19 vaccines

Medical condition to be studied
Venous thrombosis
Arterial thrombosis
Thrombocytopenia

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
330

Study design details

Outcomes
Venous thromboembolism Arterial thromboembolism Thrombocytopenia, Concurrence of arterial or venous thromboembolism with thrombocytopenia

Data analysis plan
Description of the study population characteristics, i.e. patients who have been vaccinated and have the event of interest will be described. For all study designs, we will compare the event rates in the post-vaccination risk period with the control periods using conditional Poisson regression, by type of vaccine.

Data management

Data sources

Data source(s)
Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

Data sources (types)
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