An Observational Post-Authorization Safety Study to Assess the Safety of Ad26.COV2.S Using European Healthcare Data through VAC4EU (COVID-19)

First published: 26/01/2022
Last updated: 28/06/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/48839

EU PAS number
EUPAS45362

Study ID
48839

DARWIN EU® study
No

Study countries
Netherlands
Spain

Study description
Observational Study, Retrospective observational study using electronic health care databases of various types in Europe. This study has 2 chronologically consecutive aims: 1) to conduct a feasibility assessment aiming to inform the safety evaluation study and 2) to assess the risk of developing pre-specified and newly identified AESIs following administration of Ad26.COV2.S.

Study status
Ongoing

Research institution and networks

Institutions

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

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands
First published: 07/01/2022
Last updated 10/01/2022

Institution
Laboratory/Research/Testing facility
ENCePP partner

RTI Health Solutions (RTI-HS)

France
Spain
Sweden
United Kingdom
United Kingdom (Northern Ireland)
United States
First published: 21/04/2010
Last updated 19/02/2024

Institution
Not-for-profit
ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain
First published: 05/10/2012
Last updated 23/02/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

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

Institution

Teamit Institute

Spain
First published: 12/03/2024
Last updated 12/03/2024

Institution | Other | ENCePP partner

FISABIO Valencia, Spain

Networks

Vaccine monitoring Collaboration for Europe (VAC4EU)

Belgium
Denmark
Finland
France

Germany
Italy
Netherlands
Norway
Spain
United Kingdom
First published: 22/09/2020
Last updated
22/09/2020
Network
ENCePP partner

Contact details

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Study contact

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Primary lead investigator
Fariba Ahmadizar
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
28/02/2022
Actual:
21/04/2022

Study start date
Planned:
21/05/2022
Actual:
23/05/2022

Date of final study report
Planned:
22/10/2024

Sources of funding

- Other

More details on funding

Janssen

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
EU RMP category 3 (required)

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:
This study has 2 chronologically consecutive aims: 1) to conduct a feasibility assessment aiming to inform the safety evaluation study and 2) to assess the risk of developing pre-specified and newly identified AESIs following administration of Ad26.COV2.S.

Study Design

Non-interventional study design
Cohort
Other

Non-interventional study design, other
Self-Controlled Risk Interval

Study drug and medical condition

Medical condition to be studied
Guillain-Barre syndrome

Additional medical condition(s)
Not exhaustive list

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
370000

Study design details

Outcomes
predefined and newly identified AESIs among individuals exposed to Ad26.COV2.S

Data analysis plan
For the feasibility analysis the utilization patterns of Ad26.COV2.S and other COVID-19 vaccines will be characterized and monitored over time. The primary analysis will focus on the calculation and comparison of the incidence rates of each non-acute AESI between individuals exposed to Ad26.COV2.S and (1) unexposed individuals, (2) individuals exposed to another viral vector COVID-19 vaccine (ie, Vaxzevria® AZD1222 byOxford/AstraZeneca), and 3) individuals exposed receiving a mRNA COVID-19 vaccine (cohort).For acute events, the relative risk between risk window and control window will be estimated(SCRI) among individuals exposed to Ad26.COV2.S.

Data management

Data sources

Data source(s)
Clinical Practice Research Datalink
The Information System for Research in Primary Care (SIDIAP)
PHARMO Data Network
ARS Toscana

Data source(s), other
HSD Italy, The Norwegian Health register Norway, FISABIO Spain

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