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: 11/03/2025

Study Finalised

Administrative details

EU PAS number

EUPAS45362

Study ID

48839

DARWIN EU® study

No

Study countries

- ☐ Italy
- ☐ 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

Finalised

Research institutions 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: 19/12/2025

Institution | Non-Pharmaceutical company | 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: 13/03/2025

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: 23/05/2025

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: 31/10/2025

Institution

Teamit Institute

Spain

First published: 12/03/2024

Last updated: 12/03/2024

Institution | Other | ENCePP partner

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Network | Outdated | ENCePP partner

Contact details

Study institution contact

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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: 07/03/2025

Actual: 07/02/2025

Sources of funding

- Other

More details on funding

Janssen

Study protocol

REDACTED_VAC31518COV4003-Protocol EMA Amend 1-525315_1426839 (2).pdf (1.58 MB)

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 topic:

Human medicinal product

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

Study drug International non-proprietary name (INN) or common name

COVID-19 VACCINE JANSSEN (AD26.COV2.S)

Medical condition to be studied

Guillain-Barre syndrome

Myelitis transverse

Bell's palsy

Multiple sclerosis

Autoimmune thyroiditis

Thrombocytopenia

Immune thrombocytopenia

Type 1 diabetes mellitus

Acute aseptic arthritis

Anaphylactic reaction

Asthmatic crisis

Myocarditis

Microangiopathy

Heart failure with preserved ejection fraction

Stress cardiomyopathy

Coronary artery disease

Arrhythmia

Deep vein thrombosis

Pulmonary embolism

Disseminated intravascular coagulation

Haemorrhagic stroke

Ischaemic stroke

Cerebral venous sinus thrombosis

Thrombosis with thrombocytopenia syndrome

Acute kidney injury

Hepatic failure

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.

Documents

Study results

REDACTED_CSR-Body-VAC31518COV4003-1474544_1552148.pdf (86.32 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

PHARMO Data Network

The Valencia Health System Integrated Database

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

ConcepTION CDM

CDM website

https://www.imi-conception.eu/

CDM release frequency

6 months

CDM version

2.2

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes