Incidence rates of pemphigus and pemphigoid following COVID-19 vaccines

First published: 04/07/2023

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50716

EU PAS number

EUPAS50715

Study ID

50716

DARWIN EU® study

No

Study countries

☐ Spain

☐ United Kingdom

Study description

This is a cohort study describing vaccine exposure, population incidence rates of pemphigus and pemphigoid, and incidence rates of pemphigus and pemphigoid in the vaccine exposed population. The study population is the general population in the UK and patients visiting general practices in Spain. As an exploratory analysis a Self-controlled Case Series design is applied

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Primary lead investigator

Robert Flynn

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 05/12/2022

Actual: 05/12/2022

Study start date
Planned: 05/12/2022

Actual: 05/12/2022

Date of final study report
Planned: 20/02/2023

Actual: 07/03/2023

Sources of funding

- EMA

Study protocol

FINAL_Analysis Plan - COVID-19 vaccines and pemphigoid - for publication.pdf
(465.66 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

This study aims to describe Comirnaty, Spikevax and Vaxzevria vaccine exposure, incidence rates of new onset pemphigus or pemphigoid (or related

conditions) in the general population and following exposure to Comirnaty, Spikevax or Vaxzevria vaccines. A Self-controlled Case Series is conducted as an exploratory analysis.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Self-controlled case series

Study drug and medical condition

Name of medicine

COMIRNATY

SPIKEVAX

VAXZEVRIA

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

ELASOMERAN

TOZINAMERAN

COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)

Medical condition to be studied

Pemphigoid

Pemphigus

Population studied

Short description of the study population

The study focused on general population in the UK and patients visiting general practices in Spain identified through the IQVIA™ Medical Research Data (IMRD) and THIN® databases.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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

3200000

Study design details

Outcomes

Pemphigoid and pemphigus, Vaccine utilisation will be stratified by sex, age (at first use), and year of vaccination. Event rates for pemphigoid and pemphigus in the general population will be stratified by sex, age and year of recorded diagnosis. Event rates among exposed patients will be stratified by number of doses

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Data analysis plan

This is a cohort study describing vaccine exposure, population incidence rates of pemphigus and pemphigoid, and incidence rates of pemphigus and pemphigoid in the vaccine exposed population. A Self-controlled Case Series is conducted as an exploratory analysis.

Documents

Study results

Final_Report Plan_COVID-19 vaccines and pemphigoid_v1.5.pdf(2 MB)

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

IQVIA Medical Research Data - OMOP

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