# Incidence rates of pemphigus and pemphigoid following COVID-19 vaccines

**First published:** 04/07/2023

**Last updated:** 02/07/2024

Study Finalised

## Administrative details

**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)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**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

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**Study start date**
Planned: 05/12/2022

Actual: 05/12/2022

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**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

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

Not applicable

# Methodological aspects

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**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

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**Non-interventional study design, other**

Self-controlled case series

## Study drug and medical condition

**Medicinal product name**

COMIRNATY

SPIKEVAX

VAXZEVRIA

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

ELASOMERAN

TOZINAMERAN

COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)

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**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.

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**Age groups**

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Infants and toddlers (28 days – 23 months)
- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- 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**

3.200.000

## 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

**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

## 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)**

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