# 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 institution and networks

# Institutions

## European Medicines Agency (EMA)

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Institution

# Contact details

**Study institution contact**
Robert Flynn

Study contact

robert.flynn@ema.europa.eu
**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 data collection

**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

**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