Incidence rates of vulval ulceration following Comirnaty vaccine

First published: 19/01/2023

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS50609

Study ID

50610

DARWIN EU® study

No

Study countries

☐ Spain

☐ United Kingdom

Study description

This was a cohort study describing vaccine exposure, population incidence rates of vulval ulceration and incidence rates of vulval ulceration in the vaccine

exposed population (UK & Spain). An exploratory Self-controlled Case Series was also conducted (UK only). The study population was the general female population in the UK and female patients visiting general practices in Spain.

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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Study contact

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Primary lead investigator

Robert Flynn

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 26/09/2022

Actual: 26/09/2022

Study start date
Planned: 26/09/2022

Actual: 26/09/2022

Date of final study report
Planned: 29/11/2022

Actual: 29/11/2022

Sources of funding

- EMA

Study protocol

Analysis Plan - Comirnaty and vulval ulceration - Oct 2022 - for publication.pdf
(661.81 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 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:

To describe - Comirnaty vaccine exposure stratified by age, no of doses, and year of vaccination. - Incidence rates of vulval ulceration (i) in the general population stratified by age and year, (ii) following exposure to Comirnaty vaccine stratified by age, no of doses and year, and (iii) following exposure to other COVID-19 vaccines stratified by age, no of doses and year

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Self controlled case-series

Study drug and medical condition

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

TOZINAMERAN

Medical condition to be studied

Vulval ulceration

Population studied

Short description of the study population

The study focused on general population in UK and patients visiting general practices in Spain identified through IMRD and THIN databases to determine the incidence rates of vulval ulceration and vulval ulceration in the vaccine exposed population.

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)

Special population of interest

Other

Special population of interest, other

Patients with vulval ulceration

Estimated number of subjects

880000

Study design details

Outcomes

Vulval ulceration, Vaccine utilisation was stratified by age group and number of doses. Event rates for vulval ulceration in the general population were stratified by age group and year. Event rates among exposed patients were stratified by age, and number of doses. Age was categorised as: < 10; 10-19; 20-29; 30-39; 40-49; 50-59; 60-69; 70-79; ≥80 years.

Data analysis plan

This was a cohort study describing vaccine exposure, population incidence rates of vulval ulceration and incidence rates of vulval ulceration in the vaccine exposed population (incl an exploratory Self-controlled Case Series)

Documents

Study results

FINAL_report_Comirnaty and vulval ulceration_Nov2022_for_publication (1).pdf (854.16 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)

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