Effectiveness and safety of MVA-BN vaccination against Mpox in at-risk individuals in the United States (USMVAc) (USMVAC study)

First published: 17/04/2023

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Study Ongoing

Administrative details

EU PAS number

EUPAS104386

Study ID

105127

DARWIN EU® study

No

Study countries

United States

Study description

The USMVAc (United States Mpox Vaccination) study is a retrospective, observational longitudinal study using U.S. healthcare data aggregated from HealthVerity. The study aims to evaluate the vaccine effectiveness and safety of the MVA-BN (Jynneos/Imvanex) vaccine in a cohort population of men who sex with men (MSM) and transgender women. Vaccine effectiveness outcomes include mpox infection, hospitalisation related to mpox, all-cause hospitalisation or death, all potential mpox, and all potential hospitalisation for mpox. Safety outcomes of interest include myocarditis, pericarditis, encephalitis, and anaphylaxis.

Study status

Ongoing

Research institutions and networks

Institutions

Aetion

Spain

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Institution **Other** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Elizabeth Garry

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/11/2022

Actual: 22/11/2022

Study start date

Planned: 02/05/2023

Actual: 02/05/2023

Data analysis start date

Actual: 17/10/2023

Date of final study report

Planned: 24/11/2023

Sources of funding

- EU institutional research programme

- Other

More details on funding

EMA, Aetion

Study protocol

[CLEAN] USMVac-Protocol_V0.4.pdf (6.78 MB)

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To assess the vaccine effectiveness and safety profile of MVA-BN vaccine against mpox disease among a population of MSM and transgender women in the U.S.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational study (secondary data collection)

Study drug and medical condition

Medicinal product name

IMVANEX

Medicinal product name, other

Jynneos

Medical condition to be studied

Monkeypox immunisation

Population studied

Age groups

- 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

978

Study design details

Outcomes

To compare the incidence of mpox disease, hospitalization or death among the MVA-BN fully vaccinated population (two doses at least 28 days apart), vs. unvaccinated population (no evidence of any dose) in an at-risk population of MSM and transgender women, and HIV (treated and untreated with antiretroviral treatments) subgroups. To compare the incidence of pre-specified adverse events of special interest (AESIs), namely, pericarditis, myocarditis, encephalitis, and anaphylaxis among those who were vaccinated with at least one dose of MVA-BN vs. matched unvaccinated subjects (no evidence of any dose) in an at-risk population of MSM and transgender women.

Data analysis plan

A risk set sampling of vaccinated and unvaccinated MSM and transgender women matched on age, region and insurance provider will be implemented. Additional PS matching on pre-defined covariates will be used to further manage confounding between vaccinated vs. unvaccinated MSM and transgender women. Incidence rate ratios and rate differences will be provided

to compare vaccine effectiveness and safety outcomes between vaccinated and unvaccinated subjects. For safety assessment, a self-controlled design will be implemented as a sensitivity analysis to assess potential impact of (unmeasured) time-invariant confounders.

Documents

Study results

[CLEAN] USMVac Study Report v3.0.pdf (1.02 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), other

HealthVerity United States

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Other

Data sources (types), other

Closed claims BHI, PS20 (All medical claims and pharmacy data for up to thirty-three thousand (33,000) de-identified patients for the data period covered and PS20: All medical claims for up to sixty-six thousand (66,000) de-identified patients for the data period covered Labcorp and Quest: All monkeypox lab test data for up to eight thousand five hundred (8,500) de-identified patients

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