Safety and Effectiveness of MVA-BN vaccination against MPXV infection in at-risk individuals in Germany (SEMVAc) (DRKS ID: DRKS00029638 (SEMVAc))

First published: 15/12/2022
Last updated: 15/05/2024

Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/50282

EU PAS number
EUPAS50093

Study ID
50282

DARWIN EU® study
No

Study countries
Germany

Study description
The SEMVAc study is a multi-centric prospective, non-interventional observational cohort study, which aims to investigate the following hypotheses: ? Vaccination with MVA-BN reduces the likelihood of infection with MPXV and symptomatic monkeypox disease (MPX) compared to non-vaccinated individuals. ? Pre-existing medical conditions and medication influence the risk of contracting monkeypox as a vaccinated person.

Study status
Planned

Research institution and networks

Institutions

Charité-Universitätsmedizin
First published: 01/02/2024
Last updated 01/02/2024
Institution

Med. Klinik m.S. Infektiologie und Pneumologie

Aetion
Spain
First published: 24/11/2022
Last updated 16/07/2024
Institution
ENCePP partner
Other

Harvard Pilgrim Health Care, Inc. Boston, Massachussets, USA, CVS Health Clinical Trial Services Woonsocket, Rhode Island, USA, HealthCore Wilmington, DE, USA, Humana Louisville, Kentucky, USA

Contact details

Study institution contact
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Study contact

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Primary lead investigator
Leif Erik Sander
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
30/12/2022

Study start date
Planned:
01/07/2022

Data analysis start date
Planned:
09/01/2023

Date of interim report, if expected
Planned:
07/02/2023

Date of final study report
Planned:
08/01/2024

Sources of funding

- Other

More details on funding

EMA, Intramural funds of the Charité - Universitätsmedizin Berlin and Berlin Institute of Health (BIH)

Study protocol

20221202_SEMVAc_V1.3 final_shared version.docx.pdf(534.65 KB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Other study registration identification numbers and links

DRKS-Number:,DRKS00029638,,Protocol Code:,SEMVAc

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Scope of the study:
Disease epidemiology
Effectiveness study (incl. comparative)

Main study objective:
Objectives is to investigate the followiing: -Vaccination with MVA-BN reduces the likelihood of infection with MPXV and symptomatic monkeypox disease (MPX) compared to non-vaccinated individuals. -Pre-existing medical conditions and medication influence the risk of contracting monkeypox as a vaccinated person.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(J07BX01) smallpox and monkeypox vaccines

Medical condition to be studied
Monkeypox

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
15000

Study design details

Outcomes
Vaccine effectiveness of MVA-BN against symptomatic PCR-confirmed MPX, defined as reduction in risk of infection/disease in vaccinated versus unvaccinated individuals. For study participants who have received at least one dose of MVA-BN vaccination: -Safety and reactogenicity of the MVA-BN vaccine, assessed by questionnaires -Change in risk behavior after vaccination, assessed by questionnaires -Influence of pre-existing medical conditions (e.g. HIV) and medications (e.g. HIV pre-exposure prophylaxis PrEP) on reactogenicity of the vaccination.

Data analysis plan
In this study, vaccine effectiveness, descriptive and exploratory statistical analyses are performed. The collected data will first be summarized using methods of descriptive statistics. Means and standard deviations or median with interquartile range (depending on distribution) for metric variables and absolute and relative frequencies for categorical variables (with associated 95% CI) will be used to present the results. An unadjusted group comparison will be sought and appears possible if random allocation of vaccines to study facilities results in well-comparable treatment groups. If treatment groups differ significantly by self-selection mechanisms, the framework of an emulated target trial will be used. Relevant baseline confounders (e.g. age, use of PrEP, number of sexual contacts in the past 3 months) will have to be adjusted between groups.This will be done with PS matching, depending on the exact group composition, inverse probability treatment weighting may also be used

Documents

Study report
SEMVAc_Study Report.pdf(2.65 MB)

Study, other information
Annex 2_Supplementary Material_SEMVAc_Study report.pdf(1.63 MB)

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
Prospective patient-based data collection

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