

A Protocol: Complications of Monkeypox Infection: A Systematic Review and Meta-Analysis

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Corresponding author:

ALI ALQADHIB

mr.ali-2992@hotmail.com

Author Affiliation:

Al-Ahsa Family Medicine Academy,
MOH, KSA.ALQADHIB, A; ALKHUHAIR, M; ALIBRAHEM, A; ALSARHAN, M;
ALMULIHI, Q; ALSALEH, A; ALABBAD, S; ALHABRATI, A; ALAMER, A;
ALHASHIM, I; ALSHAGHAB, M.

ADMINISTRATIVE INFORMATION

Support - Ministry of Health, Kingdom of Saudi Arabia.**Review Stage at time of this submission** - Data extraction.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202550030**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 May 2025 and was last updated on 13 May 2025.

INTRODUCTION

Review question / Objective What are the most common complications of monkeypox infection? What is the severity and outcome of these complications?

Rationale Although monkeypox has historically been considered a self-limiting zoonotic disease, recent global outbreaks—particularly the 2022 multicountry outbreak have revealed a broader spectrum of clinical manifestations and complications than previously documented. Complications such as secondary bacterial infections, encephalitis, myocarditis, ocular involvement, and severe dermatologic sequelae have been increasingly reported, especially in immunocompromised individuals, children, and individuals with untreated HIV.

However, current knowledge on the complications of monkeypox remains fragmented across case reports, small case series, and observational

studies, with significant heterogeneity in diagnostic criteria, clinical settings, and geographic contexts.

Condition being studied Mpox is a viral illness caused by the monkeypox virus, a relative of the smallpox virus. While many cases are mild and self-limiting, the disease can lead to serious complications, particularly in individuals with weakened immune systems.

Beyond the typical symptoms of fever, fatigue, swollen lymph nodes, and a characteristic rash, mpox may cause a range of complications. These include proctitis (inflammation of the rectum), pharyngitis, conjunctivitis, and tonsillitis. In more severe cases, it can affect the heart and brain, leading to myocarditis and encephalitis.

Secondary bacterial infections of skin lesions are also common and may require antibiotics. Though most patients recover with supportive care, antiviral medications like tecovirimat may be considered for severe or high-risk cases.

METHODS

Search strategy PubMed, Ovid MEDLINE, EMBASE and GOOGLE SCHOLAR are used in a defined search strategy adjusted for each database.

Participant or population Humans of any age with laboratory-confirmed monkeypox.

Intervention Infection with monkeypox virus.

Comparator Not applicable.

Study designs to be included Case reports, case series, cohort studies, cross-sectional studies, clinical trials.

Eligibility criteria

Exclusion Criteria

Animal studies, Non-human data

Non infection with monkeypox virus

Reviews, editorials

Studies without mention of complications.

Information sources PubMed, Ovid MEDLINE, EMBASE and GOOGLE SCHOLAR are used in a defined search strategy adjusted for each database.

Main outcome(s) Any complication (e.g., pneumonia, encephalitis, sepsis, ocular damage, psychiatric effects).

Data management Data will be extracted independently from the selected articles by two reviewers and stored in an electronic database. The following data will be extracted: author, year, country, study design, patient demographics, type of monkeypox (West African, Congo Basin), type of complication, outcome (recovery, sequelae, death), risk factors (if reported), during May 2025, using the following terms ("monkeypox" OR "monkeypox virus" OR "mpox" OR "orthopoxvirus") and ("complications" OR "sequelae" OR "clinical outcomes" OR "adverse effects" OR "morbidity").

Quality assessment / Risk of bias analysis

Observational studies: Newcastle-Ottawa Scale (NOS)

Case reports/series Joanna Briggs Institute (JBI) checklist

RCTs (if any): Cochrane Risk of Bias tool.

Strategy of data synthesis A systematic assessment of the available evidence will be conducted in accordance with the GRADE methodology and PRISMA checklist. A meta-

analysis will be considered if we have enough of prospective randomized trials. Our qualitative synthesis is a narrative, textual approach to summarizing, analyzing, and assessing the body of evidence included in our review, we will use the qualitative synthesis to:

- Provide a general summary of the characteristics and findings of the included studies.
- Analyze the relationships between studies, exploring patterns and investigating heterogeneity.
- Discuss the applicability of the body of evidence to the review's question within the PICO structure.
- Explain the meta-analysis (if one is conducted) and interpret and analyze the robustness of its results.
- Critique the strengths and weaknesses of the body of evidence as a whole, including a cumulative assessment of the risk of bias across studies.
- Discuss any gaps in the evidence, such as patient populations that have been inadequately studied or for whom results differ.
- Compare the review's findings with current conventional wisdom when appropriate.

Subgroup analysis Not applicable.

Sensitivity analysis Not applicable.

Language restriction None.

Country(ies) involved Saudi Arabia.

Other relevant information None.

Keywords Mpox; MPXV; DNA; DRC; WHO; HIV; FDA; ACAM2000; MVA-BN; JYNNEOS.

Contributions of each author

Author 1 - Ali AIQadhib - Drafted the manuscript.

Email: mr.ali-2992@hotmail.com

Author 2 - IBRAHIM ALHASHIM - The author provided statistical expertise.

Email: ibralhashim24@hotmail.com

Author 3 - ABDULMOHSEN ALSALEH - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.

Email: abdulmohsenalsaleh@gmail.com

Author 4 - Sajjad Alabbad - The author read, provided feedback and approved the final manuscript.

Email: sajjad_2010@hotmail.com

Author 5 - Abdullah Alhabrati.

Email: abduallahyousef@gmail.com

Author 6 - Ahmed Alamer -

Email: maxahmd@hotmail.com

Author 7 - Maitham Alsarhan -

Email: shoony2010@hotmail.com

Author 8 - Azhar Alibrahem.
Email: dr.a.alibrahim@hotmail.com
Author 9 - Mohammed Alkhudhair.
Author 10 - Qasem Almulihi.
Author 11 - Mariyyah Alshaghab.