Clinical, virological, immunological, psychosocial and epidemiological consequences of the human MonkeypoX Virus outbreak, a PROspective observational cohort study (pro-MPX)

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The aim of this study is to improve our understanding of clinical, virological, and psychosocial outcomes in patients with MPXVID. To get a better understanding of associated risk factors for MPXV infection, and to measure quality of life and stigma...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON51810

Source
ToetsingOnline

Brief title
pro MPX

Condition

- Viral infectious disorders
- Skin and subcutaneous tissue disorders NEC

Synonym
monkey-pox

Research involving
Human

Sponsors and support

Primary sponsor: GGD Amsterdam
Source(s) of monetary or material Support: ZonMW en GGD Amsterdam

Intervention

Keyword: controlled trial, homosexual men, human monkeypox, sexually transmitted infections

Outcome measures

Primary outcome

Objective

1: What is the time to resolution of symptoms among patients with symptomatic

MPXVID?

Outcome measure

1: The time between appearance of the first lesions and the day on which all

skin lesions are epithelialized and crusts fall off, and all systemic symptoms

(incl. proctitis) have resolved.

Secondary outcome

Secondary objectives and outcome measures

Objectives

2: To describe and analyse demographic, sexual and other clinical

characteristics in patients with MPXVID.

3: To describe virological outcomes in patients with MPXVID.

4: To describe changes in sexual behaviour and psychosocial outcomes in

patients with MPXVID in comparison to controls.

5: To estimate the effectiveness against MPXVID of infant smallpox vaccine

given before 1974.

6: To estimate the effectiveness against MPXVID of modified vaccinia Ankara (MVA) smallpox vaccine.

7: To describe the use of antiviral medication and/or immunoglobulins.

Outcome measures

2: Other clinical outcomes on days 4, 8, 14, 21, 28, 60 and 180, as follows:

• Clinical status of MPXVID at baseline and days 4, 8, 14, 21, 28, 60 and 180 according to a four-point ordinal scale (all lesions resolved and no serious complications* of MPXVID, active lesions and no serious complications* of MPXVID, hospitalised because of a serious complication* of MPXVID, and death).

• Proportion of patients with systemic symptoms

• Proportion of patients with proctitis

• Proportion of patients with oral lesions, pharyngitis and/or oesophagitis

• Proportion of patients requiring pain medication

• Proportion of patients requiring additional medical consultations

• Proportion of patients with a significant reduction of their quality of live (measured with DLQI with outcome above 10 points)

• Proportion of patients with secondary bacterial infection of MPXVID lesions

• Proportion of patients with scars at day 180 (measured with Vancouver scar scale).

• Demographic, sexual and clinical risk factors for MPXVID

• Co-infection(s) with sexual transmitted infections (i.e., chlamydia, gonorrhoea, HIV, syphilis, viraemic or chronic Hepatitis B infection, and

vireamic or past Hepatitis C infection)

* Definition of a serious complication: a case that is life-threatening or that results in hospitalisation or prolongation of existing hospitalisation, or results in a disability or incapacity, or results in any other complication that is considered medically significant.

3: Virological status defined by:

• Presence of MPXV DNA and cycle threshold (Ct) values in lesion swabs on baseline and days 4, 8, 14, 21 and 28.

• Change from baseline in MPXV DNA levels in anal-, pharyngeal and vaginal swabs on days 4, 8, 14, 21, 28, 60 and 180.

• Change from baseline in MPXV DNA levels in blood on days 4, 8, 14, 21, 28, 60, and 180.

• Change from baseline in MPXV DNA levels in semen on days 4, 8, 14, 21, 28, 60 and 180.

4: To describe changes in sexual behaviour and psychosocial outcomes in patients with MPXVID in comparison to controls:

• DLQI questionnaire measurement of the quality of life change at baseline and change at days 14, 28, 60 and 180 (only baseline and day 180 for controls).

• SFQ questionnaire measurement of fatigue at baseline and change at days 14, 28, 60 and 180 (only baseline and day 180 for controls).

• PHQ-SADS questionnaire measurement of anxiety, depression, somatic complaints

at baseline and change at days 14, 28, 60 and 180 (only baseline and day 180 for controls).

• Questionnaires of the experience of (internalized) stigma at baseline and change at days 14, 28, 60 (only baseline and day 180 for controls).

• Sexual behaviour measurement at baseline and change at days 14, 28, 60 and 180 (only baseline and day 180 for controls).

5: Measuring the proportion of patients with a laboratory confirmed monkeypox virus disease and of controls without MPXVID who are vaccinated with the infant smallpox vaccine before 1974, and estimate vaccine effectiveness (i.e. disease severity outcome).

6: Measuring the proportion of patients with a laboratory confirmed monkeypox virus disease and of controls without MPXVID who are vaccinated with the MVA smallpox vaccine, either as pre- or as post-exposure prophylaxis against MPX after June 2022.

7: Measuring the proportion of patients treated with antiviral and/or immunoglobulins.

Study description

Background summary

MonkeyPox Virus Infectious Disease (MPXVID) is a viral infection caused by the monkeypox virus (MPXV) which is an orthopoxvirus that is endemic in countries

in West and Central Africa. The clinical course of the MPXVID is similar to smallpox (variola) but usually milder - with less severe disease symptoms seen in the West African subtype. Historically, the case fatality ratio of MPXVID ranged from 0 to 11% and fatality occurs more commonly among children. In Europe, human MPXVID only occurred as an imported disease with limited onward transmission. However, since May 2022 over 4000 cases of MPXVID - mostly with the West African subtype - have been reported in Europe without a travel history to the endemic areas in Africa. The far large majority of patients with MPXVID in the current outbreak are GBMSM (gay, bisexual and other men who have sex with men). There is an urgent need to address essential knowledge gaps for optimal clinical care and public health management.

Study objective

The aim of this study is to improve our understanding of clinical, virological, and psychosocial outcomes in patients with MPXVID. To get a better understanding of associated risk factors for MPXV infection, and to measure quality of life and stigma, we will also include a control population of men without proctitis and MPXVID-related symptoms at day 0. In addition, we want to assess the vaccine effectiveness against MPXVID of infant smallpox vaccination given before 1974, as well as vaccine effectiveness of the modified vaccinia Ankara (MVA) smallpox vaccine, when administered as pre- or post-exposure prophylaxis in high risk contacts of MPXVID patients.

Study design

This study is designed as a prospective observational cohort study in patients with laboratory confirmed MPXVID compared with controls without proctitis and without MPXVID-related symptoms. However, patients who are being managed as a presumptive case can also be enrolled while laboratory confirmation is pending. We will also include controls without proctitis and without MPXVID-related symptoms who will only have a study visit at baseline (day 0), and day 60 and 180. A participant who is a presumptive case and subsequently tests negative for MPXV will be asked to be included as a control.

Study burden and risks

Participation in the study lasts a maximum of 180 days (6 months) from the first day of admission. Participation for cases requires 8 study visits and for controls 3. Burden: the time people spend to come to the GGD and physical burden: extra blood and swabs taken. The collection of blood and swabs belong to standard procedures of the sexual health center.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

For cases
I. Laboratory confirmed MPXVID, or
II. A presumptive MPXVID case with pending laboratory confirmation
For controls
• Individuals without proctitis and MPXVID-related symptoms

Exclusion criteria

For cases:
• Presumptive cases with subsequent negative test for MPXV (can subsequently be

included as control);
• Being under the age of 16 years old;
• Unlikely to comply with the study procedures, as deemed by the recruiting research doctor/nurse;
• Mental disorder that in the view of the investigator would interfere with adherence to the study procedures, or the decision to participate in the study;
• Investigators or otherwise dependent persons;
• Living in long term care facility.

For controls:
• Positive test result for MPXV at baseline (day 0)
• Being under the age of 16 years old;
• Unlikely to comply with the study procedures, as deemed by the recruiting research doctor/nurse;
• Mental disorder that in the view of the investigator would interfere with adherence to the study procedures, or the decision to participate in the study;
• Investigators or otherwise dependent persons;
• Living in long term care facility.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-09-2022
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	08-09-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL82230.018.22