MONKEYPOX OBSERVATIONAL COHORT

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Study description

• A multi-centre, multi-country observational cohort study to document effects of disease and treatment in patients with laboratory-confirmed monkeypox.
• Both hospitalised and community cases, whether treated with an antiviral drug (tecovirimat or other) or with symptomatic medications.
• Derived from an Expanded Use Protocol currently underway in the Central African Republic by MoH, Institut Pasteur Bangui & University of Oxford.
• Designed in consultation with the European Medicine Agency Emergency Task Force (EMA - ETF)
• In EU/EEA operated through EU-Response network in European Union and under the Ecraid umbrella.
Harmonised and collaborative science

National investigators

Belgium
France
Italy
Netherlands
Norway
Portugal
Spain
Switzerland
United Kingdom

Overall coordinating centre and sponsor: University of Oxford

Coordinating centres for
• EU/EEA: ANRS Maladies Infectieuses Emergentes
• Switzerland: and HUG (Hôpitaux Universitaires de Genève)

Protocol, CRF & other study material available at: Monkeypox Response - ISARIC

All research sites are invited to collaborate and/or use the open access study materials.
# Enrollment Criteria

<table>
<thead>
<tr>
<th><strong>Design</strong></th>
<th>Observational cohort study</th>
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<tbody>
<tr>
<td><strong>Objectives</strong></td>
<td>To describe clinical and virological outcomes in patients with monkeypox virus disease treated or not treated with tecovirimat (or other antiviral drugs).</td>
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<td>To describe safety outcomes in patients with monkeypox virus disease treated with tecovirimat (or other antiviral drugs).</td>
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| **Participants**   | Male and female patients, with:  
|                    | 1. Laboratory confirmed monkeypox virus disease  
|                    | 2. Laboratory confirmation pending, but who are being managed as a presumptive case. |
| **Planned Sample Size** | Up to 500 patients (inpatients and outpatients) |
## Objectives & outcome measures

<table>
<thead>
<tr>
<th>Primary</th>
<th>Objectives</th>
<th>Outcome Measures</th>
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<td>To describe clinical outcomes in patients with monkeypox virus disease treated or not treated with tecovirimat (or other antiviral drugs).</td>
<td>Time to lesion resolution, defined as the first day on which all lesions are scabbed or desquamated, and absence of any serious complications, up to 14 days post treatment.</td>
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## Objectives and outcome measures

<table>
<thead>
<tr>
<th>Secondary</th>
<th>To describe <strong>clinical outcomes</strong> in patients with monkeypox virus disease treated or not treated with tecovirimat (or other antiviral drugs).</th>
<th>a) Clinical status on day 14 and day 28 according to a <strong>four-point ordinal scale</strong> (all lesions resolved and no serious complications, active lesions and no serious complications, hospitalised because of a serious complication of monkeypox, and death).</th>
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<td>a) Evidence of <strong>recrudescence or relapse</strong> at D60 and D180.</td>
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<td>To describe <strong>virological outcomes</strong> in patients with monkeypox virus disease treated or not treated with tecovirimat (or other antiviral drugs).</td>
<td>a) Change from <strong>baseline in Monkeypox virus DNA levels in throat swabs</strong> on days 4, 8, 14 and 28.</td>
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<td>a) Change from baseline in Monkeypox virus DNA levels in <strong>blood</strong> on days 4, 8, 14 and 28 (hospitalised patients only).</td>
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<td></td>
<td>a) Presence of Monkeypox virus DNA in <strong>lesion swabs</strong> on days 4, 8, 14 and 28.</td>
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</table>
OTHER COMPONENTS OF OUTBREAK PREPAREDNESS AND RESPONSE
Expanded Use Access Protocol of tecovirimat in the Lobaye prefecture of the Central African Republic

Tripartite agreement between the Ministry of Health (Central African Republic), Institut Pasteur de Bangui & University of Oxford

Registration ISRCTN43307947

Monkeypox cases treated for 14 days with tecovirimat and followed up for 28 days with PCR

14 cases recruited in the first season
ISARIC-WHO Clinical Characterisation Protocol for Severe Emerging Infection

Observational protocol for harmonized collection of data and samples.

Registration ISRCTN66726260

Hospitalised patients followed during admission.

15 cases recruited since April 2022. 86% male; 24-59 years
Efficacy of Tecovirimat for the treatment of non-hospitalised patients with confirmed monkeypox - research brief | NIHR

SYNOPSIS

• Double-blind, placebo-controlled, RCT
• non-hospitalised adults and children with laboratory-confirmed monkeypox in the UK
• randomly allocated (1:1) to receive tecovirimat or matching placebo for 14 days, in addition to the usual NHS care.

Outcomes:
• Clinical: time to (a) active lesion resolution and (b) complete lesion resolution.
• Microbiological: (viral culture and viral DNA level in throat swab samples)
• For the main analyses, follow-up censored at 28 days after randomisation.
• Safety: SAEs, SUSARs, non-serious AEs of special interest
THANK FOR YOUR ATTENTION