



UK Health
Security
Agency

Longitudinal Immunology of Monkeypox virus Infection (LIMIT) study

On behalf of the UK Health Security Agency (UKHSA), we would like to invite you to [take part in the LIMIT study](#) but before you decide, please read the following information.

Why you've been invited

You have been identified by your hospital trust because you have:

- been diagnosed with mpox (monkeypox), and or
- recently been vaccinated against mpox

You have been invited because we would like you to take part in our study. We would like to understand how your antibody levels differ over time, as well as between having had mpox or having been vaccinated against mpox.

Taking part

Taking part is entirely voluntary. If you wish to take part, you will be asked to complete an [online consent form](#).

If you think answering questions about having mpox or being vaccinated will cause you to feel worried or anxious, we recommend you do not take part in this study.

If you do take part and the questions affect you, we recommend you visit [Queer Health](#) for more information if this is what you require.

If you feel you need more physical or mental support, then contact NHS 111 or your usual healthcare provider.

You can stop taking part and email to withdraw your consent if you have already done so.

Benefits and risks

The advantage of taking part is to help the knowledge base around mpox, so we can identify the body's reaction to the monkeypox virus, which will help us understand and develop isolation guidance.

You will receive a £10 online amazon or similar voucher after 3 months of participation, and a further £15 voucher after having taken part for the full year. The small disadvantage to participation is the requirement for a blood sample, which can cause mild discomfort and bruising. There is also a very small risk of infection with blood taking.

Withdrawing from the study

Once the study has started, you can withdraw at any time, including after you have had your blood test taken. We would then remove your results from the data set and your consent form would be deleted.

The study

The study is being run by the UKHSA Rare and Imported Pathogens Laboratory, Porton Down. The study is being organised by the above groups and is being funded by UKHSA with a grant from CEPI, supported by local NHS hospital trusts. The study is being led and sponsored by UKHSA.

The study protocol has been reviewed by an independent expert and ethical approval has been granted from the NHS REC.

Purpose

The monkeypox virus has been identified in the UK in large numbers since May 2022. The virus originates from Africa, and was first identified in monkeys, although its primary reservoir is more likely to be rodents. Monkeypox virus can cause lymphadenopathy, fever, myalgia, and commonly, vesicles, umbilicated papules and ulcers. Prior to this year, mpox had only been identified on occasions in the UK and was associated either with travel to an endemic area or close contact with someone who had travelled to an endemic area.

Monkeypox spreads primarily via skin-to-skin contact of cutaneous lesions but has also been known to spread via respiratory route.

It is not well described how the body immune system reacts to exposure to monkeypox virus, either after contracting the virus or having had the vaccine. We are aiming to measure antibodies following exposure to the virus to compare antibody levels between virus infection and immunisation.

What the study involves

If you choose to participate, you will be asked to complete a short online questionnaire. If you had mpox, we will ask you about when:

- your symptoms started
- you were tested
- your symptoms stopped

This data is all anonymised.

If you were vaccinated against mpox, we will ask you why you were vaccinated, and when. This data is all anonymised.

After completing the questionnaire, you will be posted a kit to take some home testing blood samples to test for antibodies to mpox. You will be asked to do this once a month for a blood test to measure your antibodies for the first few months and as we gather more data, we will ask for blood less often.

We anticipate this study will run for 12 months and will likely ask for blood at 1, 3, 6 and 12 months, although this could change. You will be asked to post this back with a prelabelled self-return box. Around the time of each blood sample request, we will ask you to answer further questions via an online questionnaire, which will ask you, since your last visit, if you've had:

- a vaccine, if you hadn't already had one
- a second vaccine, if you'd already had one
- mpox, if you hadn't already had it

The consent process is done online via a website called SelectSurvey, and all data is stored on the SelectSurvey Web Host application and then imported to a survey database within the UKHSA network. Database access will be restricted to the study team. Data for this study will be held for five years then deleted.

Your blood results will be stored in the Rare and Imported Pathogen Laboratories electronic patient records under your anonymised identity. They will be used by the study team for analysis. The study team comprises UKHSA researchers.

If you wish to receive your results, you will get a text message should you provide us a number. This will tell you if your antibodies are positive or negative. This information is for research use only and cannot be used to guide your treatment or isolation need, but it may inform us for future guidance surrounding the need for isolation. You do not have to receive your results.

Your blood will be stored at the serosurveillance laboratory in Porton Down. It may then be used for test development, subject to appropriate ethical approval.

You are welcome to take part in any treatment trials that are offered while participating in this study.

After the study

The results of the study are likely to be written up and published in a peer reviewed article as well as presented verbally at professional meetings to infection and public health specialists at your local hospital and nationally. None of the information shared will identify any participant in the study. All reports generated will be fully anonymised.

Data protection

In this research study we will use information from you, collected by an online questionnaire via a website. We will collect only information that we need for the research study. Your data will be stored on secure drives and will be password protected.

Confidentiality

The information you provide is totally confidential and handled in accordance with the Data Protection Act 2018 and the UK General Data Protection Regulation (UK GDPR). All data will be entered into a UKHSA hosted web server (<https://snapsurvey.phe.org.uk>).

Data security

Your information will be held securely by UKHSA and securely protected at all times, with access restricted to a small number of staff working on the survey. All members of the study team have been specially trained to protect your confidentiality.

Data for this study will be entered into a web survey delivered by the SelectSurvey Web Host application. Database access will be restricted to the study team. Data for this study will be held for 5 years then deleted.

This information will only be used by the research team for this survey. We will keep all identifiable information about you securely within UKHSA and in keeping with strict data protection regulations.

You can stop being part of the study, without giving a reason, including after your blood has been taken.

Find out more about how your information is used

You can find out more about how we use your information by sending an email to the UKHSA data protection officer at InformationRights@UKHSA.gov.uk

Data handling procedures are in accordance with the General Data Protection Act 2018 and GDPR. Data will be anonymised and stored by the Rare and Imported Pathogens Laboratory but will be shared anonymously across UKHSA. Anonymised results will also be shared with participating NHS trusts.

[Further detail on how UKHSA handles and protects your data](#)

Contact us

If you have a concern about any aspect of this study, please email limitstudy@ukhsa.gov.uk and researchers will do their best to answer your query. They will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact limitstudy@ukhsa.gov.uk or call 01980 612 348 from 9am to 5pm, Monday to Friday.

Complaints Manager
Strategy Directorate
UK Health Security Agency
Nobel House
17 Smith Square
London
SW1P 3JR

Alternatively, you can email RandD.OFFICE@phe.gov.uk

If you agree to take part, would like more information or have any questions or concerns about the study please contact limitstudy@ukhsa.gov.uk

Thank you for taking the time to read this information.

Once you've completed the consent form and the questionnaire, you will need to email limitstudy@ukhsa.gov.uk with your unique participant identifier and the address you would like your postal home blood sampling kit sent out to.

[Take part in the LIMIT study](#)