The MELODY Study

Mass evaluation of lateral flow immunoassays (at home finger prick antibody tests) for the detection of SARS-CoV-2 antibody responses in immunosuppressed people

This is an antibody research study. Antibodies are made by the immune system to fight infection. In this study, we aim to

1. Assess how many immunocompromised people have detectable antibodies against COVID-19 following 3 vaccines. Antibodies will be tested using a finger prick testing kit we send to your home.
2. Investigate whether lack of detectable antibodies are associated with risk of infection over a 6-month period.
3. Investigate what factors are associated with lack of detectable antibodies in immunocompromised people, e.g. the type of immunosuppressant medication you receive. This will be determined by asking you to complete an online questionnaire with your antibody results.

The study aims to recruit people who have received solid organ transplants, people with rare autoimmune diseases receiving immunosuppression and people who have had a diagnosis of blood cancer.

At this time, antibody testing results should not be used to alter individual behaviour as there is still a lot to learn about this virus. A positive test does not mean that you are fully protected from getting COVID-19 or passing on the virus, and a negative test does not mean you do not have antibodies that may provide protection against COVID-19. Whatever your test result, it is important that you continue to follow the current Government advice on www.gov.uk.uk/coronavirus.

Who is running this research?

This research is being run by doctors and researchers at Imperial College London, NHS Digital, NHS Blood and Transplant, University of Southampton, University of Cambridge, University of Nottingham and Ipsos MORI, an independent research organisation. The research is funded by the Medical Research Council (MRC) in collaboration with health charities (Kidney Research UK, Vasculitis UK, Blood Cancer UK and the Cystic Fibrosis Trust).

Why have I been invited to take part?

You have been invited to take part in this study because you are an adult who has received a solid organ transplant, or you have been identified by the National Disease Registration Service (NDRS) as someone who may have a rare autoimmune disease or a form of blood cancer.

Please note that if you are a transplant patient, then in a small number of cases, the information stored in the NHS Blood and Transplant registry is incomplete and this may prevent you registering. In this case, we apologise and suggest you call the FREEPHONE number **0800 819 9150**, to assess whether this error may be corrected.

What if I have tested positive for COVID-19?

As long as you have had your third vaccine dose, we would like you to participate. We can tell whether, and when, you have had a positive SARS-Cov-2 test from our linkage with national COVID surveillance.

Do I have to take part?

No. Whether you take part in the study is entirely up to you. Even if you do decide to take part, you can change your mind at any time without giving a reason. You should be aware that data collected about you up to the time you decide to stop taking part may still be used as part of the research study results. If you have received the test and then decide you don't want to take part anymore, please throw away the testing kit securely with your regular household waste, being careful to keep it out of reach of children and pets.

What is involved?

In this study we are inviting you to:

A. Complete an online questionnaire

After registering your consent, we would like you to complete a questionnaire on our secure internet portal about your health and any immunosuppressive medication you might be taking. We will also ask you your contact details.

You do not have to answer all of the questions if you choose not to.

At the end of the questionnaire, we ask you to give your consent for your data to be linked to other national datasets of NHS and health data so that we can assess

whether having antibodies influences the risk of COVID-19 infection and its severity in immunosuppressed people over the 6 months following third vaccination.

B. Perform an antibody test on yourself at home

Once you have completed section A, an antibody testing kit will be delivered to you.

You will need to read the instructions of the self-administered antibody kit and do the test on yourself at home. This will take approximately 30 minutes in total. The test looks a bit like a pregnancy test but uses a drop of blood taken from your finger. All the equipment needed to take the test will be provided, and includes a wipe to clean your finger, a lancet (covered fine needle) to prick your finger and create a droplet of blood and the testing stick which includes a well to collect a drop of blood. Please read the instruction booklet sent with the test for detailed guidance on taking the test, which is important as the test also looks like the 'lateral flow' tests which are used to detect infection.

Although you can take this test by yourself, if you need help you can ask someone from your household to assist you.

We would like you to perform this test between 21 days and three months (90 days) after you have received your third COVID-19 vaccine dose.

Please note that we have secured enough home-kits to test 36,000 participants; in the unlikely event that these have all been sent out, we would still like you to complete the online questionnaire.

C. Upload results and undertake a survey about your COVID risk

Once you have completed your test, we will ask you to upload the results of the test onto the study web portal via your login in, by:

1. Recording your test result if completed.
2. Upload a photograph of your test result if completed (this step is optional).

We will also ask you some questions related to what your exposure to COVID-19 has been.

It is very important that only the named person who registered to take the test and who was sent the testing kit takes the test.

If you do not have access to the internet, you can call the FREEPHONE number **0800 819 9150** and take part over the phone.

If you consent to being contacted again for future research studies, we may contact you by phone or email after completing the antibody test to take part in some further research. If you consent to being contacted again, you do not have to say whether you would actually take part in the research, just whether you would be happy to be contacted about it. Participation will be entirely voluntary.

How will this research help others?

The study aims to estimate how many immunosuppressed people in the UK have antibodies that may provide protection against COVID-19 after 3 vaccines and then assess whether people with antibodies have lower rates of infection and severe outcomes of infection than people without antibodies. We don't know yet if having antibodies gives someone who is immunosuppressed long-lasting protection from the virus. The results of this study may help assess the impact of the vaccines on the level of antibody response to COVID-19 across the UK and help guide public health policy towards vulnerable groups.

For more information on the Government's response to COVID-19, please visit www.gov.uk/coronavirus.

What do the antibody test results mean?

Antibodies are made by the immune system to fight infection. This test looks for two types of antibodies, IgM, which are often short-lasting, and IgG, which are usually longer lasting. By looking for antibodies in blood, we can better understand how many of the transplant and immunosuppressed patient groups in the UK have developed an antibody response to COVID-19 following their third COVD-19 vaccine.

Please be aware that the antibody test is not 100% accurate at an individual level. A positive test does not mean that you are fully protected from getting COVID-19 or passing on the virus, and a negative test does not mean you do not have antibodies that may provide protection against COVID-19. We appreciate that because of your clinical condition, you may still be taking precautions and modifying your behaviour to avoid COVD-19 infection.

Therefore, whatever your test result, we ask that **you follow government advice and continue with whatever precautions you were using prior to the test.**

What are the possible risks or side-effects of taking part?

Collecting the blood sample for the self-test requires a finger prick which can feel like a little pinch, which may cause some people a small amount of discomfort. For those patients on blood thinning medication, we also ask that the cotton wool swab supplied is used to press on the area of the finger prick test, until bleeding is stopped.

Who has reviewed the study?

To protect your interests, all research at Imperial College London is reviewed by an independent group of people called a Research Ethics Committee. This study has been reviewed and it has been granted 'favourable opinion' by the London-Central Research Ethics Committee.

How do I take part?

You would have been informed about the study in one of two ways:

1. You would have received an individualised invitation letter
2. You would have been informed about the study either through your clinical teams, social media or health charities.

All information will lead you to the secure study portal, where there will be access to further information.

We would next like you to consent to take part in the study (as outlined above). We would like everyone to take part in the online questionnaire. Once this is complete, you will be sent an antibody kit. Once the antibody test has been performed, we would ask you to log back into the study portal and upload your results and perform a second questionnaire about your COVID-19 exposure risk.

Altogether, we estimate the questionnaires will take about 15 minutes each, and the antibody test 30 minutes.

If you have difficulty using the online portal, you can call the FREEPHONE number **0800 819 9150** for assistance with completing any part of the research.

What will happen to the results of this research study?

Once analysed, the results of the study (**which do not contain personal identifiable information**) will be shared with the Department of Health and Social Care, the funders and scientists from the Research Team to help understand how many people in the UK have antibodies that may provide protection against COVID-19.

Will you need to collect any information about me?

We will need to collect some details about you, including your name, age, gender, and ethnicity. If you are a transplant patient, we will also ask for your address.

We will ask for details of any vaccinations you may have had for COVID-19. We will ask you about your home and work life, your health, your thoughts on COVID-19 and antibody testing. We will also ask you specific questions about your medical condition(s) and treatments.

Confidentiality

It is extremely important to us that we maintain your confidentiality about taking part in this study. All information collected about you will be used and stored securely to protect and respect your identity. Your data (the information collected about you) will be given a unique study number to make sure you cannot be identified from your data. Only the Research Team at Ipsos Mori, NHS Blood and Transplant or NHS Digital will be able to match your name to the unique study number, if it is necessary to do so.

If you consent to take part in the research your name will not be shared outside the Research Team. We confirm that your personal data will never be available to the general public in any circumstances. The results of this research are likely to be published but will not contain any personal information which could identify you. Please keep this information sheet for reference.

What will happen with the information I provide?

Imperial College London, NHS Digital and NHS Blood and Transplant are joint data controllers for the processing of personal data for this survey, which means that they are responsible for ensuring that the processing complies with the General Data Protection Regulation (GDPR).

Ipsos MORI is a data processor, acting on behalf of Imperial College London, NHS Digital and NHS Blood and Transplant. They will only keep your data in a way that can identify you for as long as is necessary to support the research project and findings. By end of March 2022 Ipsos MORI will delete your personal contact data from their systems.

If you consent to being contacted for future research, and/or you agree for the results of this study to be linked to other health information that the NHS holds about you (e.g. GP health records), NHS Digital and NHS Blood and Transplant may keep your data for up to 10 years in order to support this research. That includes the contact details you provide to Ipsos MORI. If you have consented to data linkage, we may receive your contact details from the NHS and, if you have consented to be contacted for future studies we may use them to contact you.

Researchers who wish to access the data from this study and/or to contact participants about future research will need to have a legitimate reason to do so, the approval of a Research Ethics Committee and will have to apply to a data access committee composed of at least 3 of the study investigators (from NHS Blood and Transplant, NHS Digital and Imperial College London), and at least one public representative.

Legal Basis

We use personally identifiable information during this study to conduct research to improve health, care and services.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

Our legal basis for using your information under General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

- performance of a task carried out in the public interest" (Article 6(1)(e) in the GDPR).
- Where special category personal information is involved, we rely on "scientific or historical research purposes or statistical purposes (Article 9(2)(j) in accordance with Article 89(1) in the GDPR)".

The National Disease Registration Service operate under the National Disease Registries Directions 2021. The legal basis for processing your information is under Sections 254(1) and 254(6) of the 2012 Health and Social Care Act (the 2012 Act).

Do you share my information with others?

To run this COVID-19 testing research Ipsos MORI works with a number of supplier organisations involved in the print and despatch of invitation letters and testing kits, mail and text message services and online data collection. These suppliers are all approved and compliant with the Genera Data Protection Regulations. Any third party service providers are required to enter into data processing agreements and will only be permitted to process your personal data for specified purposes and in accordance with Imperial College, NHS Digital and NHS Blood and Transplant policies.

If you consent to be re-contacted, NHS Digital and NHS Blood and Transplant may share your personal data with certain researchers as outlined above. Any research study would require full ethical approval.

What are my choices about how my information is used?

You can stop taking part in the study at any time, without giving a reason, however once your data has been included with the rest of the study data and analysed, it is not possible to remove your specific data from the results.

Where can I find out more about how my information is used?

You can find out more about how your information is used at www.hra.nhs.uk/information-about-patients, or by asking one of the Research Team, by sending an email to uk-melodystudy@ipsos.com.

Our insurance statement

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigators on uk-melodystudy@ipsos.com. The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Joint Research Compliance Office.

How to make a complaint

If you are concerned because you have received an invitation letter to participate, but you do not think they have a rare autoimmune disease or cancer, please contact NDRSenquiries@nhs.net (with the subject line of "MELODY study invitation enquiry") or by post: Director, NDRS, 2nd floor, The Government Hub, 23 St Stephenson Street, Birmingham B2 4BH.

If you wish to raise a complaint on how we have handled your personal data, please contact:

Ipsos MORI's Data Protection Officer via email at compliance@ipsos.com with "COVID-19 home testing (21-086406-01)" in the email subject line, and/or via post COVID-19 home testing (21-086406-01), Compliance Department, Market and Opinion Research International Limited, 3 Thomas More Square, London E1W 1YW, United Kingdom.

Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on **020 7594 3502** and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

NHS Digital's Data Protection Officer, Kevin Willis via email nhsdigital.dpo@nhs.net

NHS Blood and Transplant's Data Protection Officer, Katrina Smith, via informationgovernanceteam@nhsbt.nhs.uk

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (Imperial College London) first before involving the regulator.

Additional contact details

If you have further questions about this study, please contact the Research Team, email uk-melodystudy@ipsos.com.

Thank you for taking part in this research.