Participant Information Sheet

COVID-19 capillary and venous blood antibody testing study

Summary

- Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.
- Please take the time to read the following information carefully. Discuss it with friends and relatives if you wish.
- You are free to decide whether or not to take part in this research.
- Please do ask us if there is anything that is not clear or if you would like more information.
- This study aims to determine whether dried blood spots, collected either by a finger prick blood test or a new blood collection device called OneDraw, provide the same antibody test result for COVID-19 (an indication that a person has had the COVID-19 infection or vaccination) as blood taken from a vein in the arm.
- We would like you to provide three blood samples. These will be taken by a study team member in one visit at the MRC Epidemiology Unit in Cambridge or Ely. Samples will be taken from a vein in your arm, from a finger prick test and from your upper-arm using a OneDraw device. We will ask you to complete a short web-based questionnaire with basic information about yourself.
- The information and results collected will be used for research purposes only.
- Thank you for considering supporting our research.

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If you have any questions about this study please talk to:
The Capillary And Venous Antibody Study Team
Email: cava.study@mrc-epid.cam.ac.uk

1 Why we are doing this study

What are we studying?

We are conducting this study to determine if dried blood spots, collected either by a finger prick blood test or the OneDraw device, provide the same antibody test result for COVID-19 (an indication that a person has had the COVID-19 infection or vaccination) as blood taken from a vein in the arm (venous sample).

We will take blood using these three methods in participants who have previously been tested for COVID-19 antibodies in order to select a range of people without antibodies and those with antibodies, whether or not they had symptomatic COVID-19.

2 Why am I being asked to take part?

We are recruiting participants from the NIHR BioResource who have already had a COVID-19 antibody test and who have agreed to be approached for future studies. We will recruit participants who have tested either positive or negative for COVID-19 antibodies, and those who have had symptoms of COVID-19 and those who have not. Participants in this study will need to be over the age of 18.

3 What will happen to me if I take part?

If you agree to help us with this research, we will send you a link to complete an online consent form. We will then ask you to fill in a short online questionnaire. The questionnaire will ask for your date of birth, gender, whether you have had COVID-19 and other symptoms in the past and how severe these symptoms were (a list of these symptoms can be found in the appendix at the end of this document), whether you have had a COVID-19 antigen or PCR test, whether you have had an antibody test other than that from CUH Occupational Health and the results of these tests, and whether you have received a vaccine against COVID-19.

One of the questions asks you to confirm that you are not currently experiencing COVID-19 symptoms (high temperature, new persistent cough, or change in sense of taste or smell). You will not be able to participate in this study if you have current symptoms. Nor will you be able to participate if it has been less than 21 days since the commencement of COVID-19 symptoms or less than 14 days since a positive COVID-19 antigen or PCR test.

You will be invited by email to come into a secure area in the Clinical Research Facility at the MRC Epidemiology Unit, either in Cambridge or Ely. A member of our study team will collect a venous blood sample, finger prick blood sample and a OneDraw blood sample from your upper arm. The OneDraw device attaches to the upper arm using a special adhesive, the sample is taken by the push of a button and is stored as a dry blood spot on special paper https://www.drawbridgehealth.com/onedraw.
In a study of the OneDraw device, participants reported that it was less painful than standard blood collection methods, including both finger prick samples and blood taken from a vein in the arm. The total amount of blood to be taken is equivalent to less than 2 teaspoons of blood.

At the end of the study, we will provide you with the results of the antibody test, unless you indicate on the consent form that you do not wish to receive it.

4 Possible benefits and disadvantages of taking

What are the possible benefits of taking part?

There are no personal benefits of taking part in this study, but you will be helping and contributing to research in establishing whether dried blood samples can be used for COVID-19 antibody testing, which could lead to COVID-19 antibody test being more widely available. The method requires less blood and can be used remotely.

What are the possible disadvantages and risks of taking part?

Participation in the study requires giving three blood samples. These samples could cause temporary pain and discomfort at the time or bruising. All blood samples will be taken by a trained staff member in a clinical setting where facilities are available to support anyone who feels unwell.

5 More information about taking part

Do I have to take part?

No, it is up to you to decide whether or not to take part in this study. You are free to withdraw at any time, without giving a reason. If you decide to withdraw, the MRC Epidemiology Unit will keep any information and samples that they have already collected about you. Any information will be stored securely and only accessible by the CAVA study team.

Will I receive any payment for taking part?

Unfortunately, it will not be possible to provide payment for taking part. Reasonable travel expenses will be reimbursed.

What if there is a problem?

If you have a concern about any aspect of this study you should ask to speak to the research team who will do their best to answer your questions at:
Cava.study@mrc-epid.cam.ac.uk.

If you remain unhappy and wish to complain formally, the normal University of Cambridge complaints process is available to you through the University of Cambridge Clinical School Secretary: telephone: 01223 333543 or email: SchoolSec@medschl.cam.ac.uk.

In addition, you can also contact the Cambridge University Hospitals NHS Foundation Trust Patient Advice and Liaison Service (PALS): telephone: 01223 216756 or email: pals@addenbrookes.nhs.uk.

Cambridge University Hospitals NHS Foundation Trust, is a member of the NHS Clinical Negligence Scheme for Trusts, and will accept full financial liability for harm caused to participants in the study caused through the negligence of its employees and honorary contract holders. There are no specific arrangements for compensation should a participant be harmed through participation in the study, but no-one has acted negligently. The University of Cambridge will arrange insurance for negligent harm caused as a result of protocol design and for non-negligent harm arising through participation in the study.

What will happen to information about me collected during the study?

With your permission, information we collect will be stored anonymously at the MRC Epidemiology Unit, University of Cambridge. You will be assigned a unique code when you first take part in CAVA. This code will be used to label all data collected during the study and is used in place of personal information. Personal identifiable information, such as the contact details we use to keep in touch with you, will be kept separate from any other data we collect. The database containing personal information is on a secured network drive on computers in the MRC Epidemiology Unit, University of Cambridge.

Cambridge University Hospitals NHS Foundation Trust (CUHNFT) and University of Cambridge are joint sponsors for this study based in the United Kingdom. CUHNFT and the University of Cambridge will be using information from you in order to undertake this study and will act as joint data controllers. This means that both organisations are responsible for looking after your information and using it properly. CUHNFT and the University of Cambridge will keep identifiable information about you for 1 year after the study has finished and it will then be destroyed.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.
You can find out more about how we use your information at:

- https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data/
- https://www.hra.nhs.uk/information-about-patients/
- Or by asking one of the research team by email: cava.study@mrc-epid.cam.ac.uk

For Cambridge University Hospitals NHS Foundation Trust, please visit: https://www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/looking-after-your-information, or email the Data Protection Officer at: gdpr.enquiries@addenbrookes.nhs.uk

For University of Cambridge, please visit: https://www.medschl.cam.ac.uk/research/information-governance/, or email the Information Governance team at: researchgovernance@medschl.cam.ac.uk

What will happen to any samples I give?

Any samples that are collected during the study will be processed and stored by the MRC Epidemiology Unit. Your unique CAVA code will be used to label all samples collected during the study so none of your personal data is put on the blood tubes. With your consent, and with the appropriate research ethics approval, retained samples and linked data may be used for future research, which may include collaborations with academic parties and the commercial sector both within and outside the UK.

What will happen to the results of the study?

When the study is completed, the results will be presented at scientific meetings and published in peer reviewed journals and made available on the MRC Epidemiology Unit website. We expect that results will become available within a year after completing the sample collection. If published, your identity and personal details will be kept confidential. No information that could identify you, like your

name, will be published in any report about this study.

Who is organising and funding the study?

This study is organised by the MRC Epidemiology Unit, part of the University of Cambridge. The funder is the Medical Research Council.

Who has reviewed the study?

This study has been reviewed by an independent group of people, the Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. The study has been given a favourable opinion by North West - Haydock Research Ethics Committee Research Ethics Committee.

6 Contact for further information

If you have any questions regarding the study or how you might be involved, further contact information can be found below:

The CAVA Study Team
Email: cava.study@mrc-epid.cam.ac.uk

Principal Investigator

Prof Nicholas Wareham
Unit Director
MRC Epidemiology Unit, University of Cambridge

7 Appendix 1

List of current COVID-19 symptoms:

- New persistent cough
- High temperature
- Change of taste or smell
- Hoarseness (changes to the sound of your voice, particularly becoming strained)
- Non-persistent cough (not coughing continuously)
- Discharge or congestion in the nose
- Sneezing
- Sore throat
- Feeling breathless
- Wheeze (a whistling sound when breathing)
- Headache
- Muscle aches
- Joint pains or aches
- Unexplained tiredness
- Being sick or feeling sick
- Loss of appetite
- Diarrhoea

Thank you for taking the time to consider taking part in this study.