Capillary Testing for COVID-19 in People with and without Diabetes (CTC-19 Diabetes) Study

- Before you decide whether you wish to help, it is important for you to understand what is involved. Please take the time to read the following information carefully.
- Taking part is completely voluntary, it is up to you whether you decide to take part. If you take part, you can withdraw from the study at any time and you do not need to give a reason.
- These are challenging times for us all. Please ask us if anything is not clear or you would like further information.

What is the purpose of this study?

Since first reported in December 2019, coronavirus (COVID-19) has led to a global pandemic. It has become clear that some individuals who have other conditions including diabetes are at increased risk from the complications of COVID-19. We have developed a test for antibodies to SARS-CoV-2 which works on tiny volumes of blood. This means we can collect small blood samples by post and work out who had had the infection even if they have had a vaccine.

In this study we will use postal collection of small volume capillary blood samples to study the effects of COVID-19 on people with diabetes compared with those who do not.

Who is eligible to take part in this study?

- Members of the general population who may or may not have had COVID-19 and have been diagnosed with diabetes
- Members of the general population who may or may not have had COVID-19
- Be aged 18 or over, there is no upper age limit

- For people that are shielding, we recommend that a member of your household visit a post box on your behalf to return samples

Who is not eligible to take part in this study?

- Being identified as unsuitable to participate following guidance of their clinician for instance the immunocompromised and individuals on blood thinning medications

What will taking part involve?

- Completing a consent form
- Completing a questionnaire about you (and your diabetes, if applicable) and any COVID-19 symptoms you may have experienced

Providing a capillary blood sample (by finger prick) via a postal collection. Full instructions will be sent with the kit detailing how samples should be collected and returned to us by Royal Mail Freepost, using an ordinary post box.

Repeat samples

If you have given your consent for us to contact you, we may ask you to provide repeat capillary finger prick samples in the future. You are under no obligation to give further samples.

What are the possible benefits of taking part?

There is no direct benefit to you from this study. Samples collected will be used to study how COVID affects people with diabetes and the prevalence of COVID infections in the general population. We will not report results to participants.

What are the possible disadvantages and risks of taking part?

You could have discomfort and soreness at the site of the finger prick test.

We ask you to follow government guidance in place with regard to social distancing and returning your sample pack to us. For people that are shielding or self-isolating we recommend that a family member or friend visits the post box for you.

How will my information be kept confidential?

All information that is collected about you during the course of the study will be kept strictly confidential using strict University of Bristol data protection

policies. Any information that leaves the co-ordinating centre will have your name and address removed so that you cannot be recognised from it.

What will happen to my blood sample(s)?

Capillary blood samples in this study are tested for COVID-19 antibody.

Samples we collect are stored using a unique code which can only be traced back to yourself via a secure database with restricted access.

Some samples we collect may be sent coded and anonymised to national and international research laboratories for further research. Any results and correspondence will be made using this code and strict data protection guidelines will be adhered to.

If you have given your consent your sample(s) will be stored to allow us to go back to them in the future should new techniques/research questions be developed.

Should you wish to do so, you can request that your samples be destroyed at any time.

General Data Protection Regulation (GDPR) Information:

The University of Bristol is the sponsor for this study based in Bristol, United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

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 piece of information possible.

The only people in the University of Bristol who will have access to information that identifies you, will be people who need to contact you to provide study updates or audit the data collection process. The people who analyse the information will not have access to identifiable data.

You can find out more about how we use your information under the GDPR statement: http://www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/

What will happen to the results of the research study?

Results from the research will be published regularly in peer reviewed scientific journals.

What if there is a problem?

It is highly unlikely that anything will go wrong. If taking part in this research project harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay your legal costs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study please contact the Chief Investigator Professor Kathleen Gillespie using the details given at the end of this leaflet.

Who is organising and funding this study?

This study is internally funded and will result in data to facilitate a targeted funding application.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given favourable opinion by the South West - Central Bristol REC.

Who should I talk to if I have any questions or concerns?

You are encouraged to ask all questions which come to your mind about the study. Please contact us using the details below:

Contact us:

Chief Investigator: Professor Kathleen Gillespie

Research Technician: Ms Rachel Aitken Study Administrator: Mrs Isabel Wilson

Telephone: 0117 414 7915 or 0117 414 8058

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