

CLARITY STUDY Patient information: Sub Study

Understanding how long IBD patients carry the COVID-19 virus.

Patient information sheet

Thank you for taking the time to read this leaflet. You are being invited to take part in an additional part of the CLARITY IBD research study. Before you decide, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please contact your local research nurse or a member of the central research team in Exeter on 01392 406850.

What is the purpose of the study?

Two weeks after a confirmed COVID-19 infection most people have cleared the virus and if re-tested have a negative PCR swab test. However, some people may carry the virus at low concentrations for longer, even without symptoms. A positive PCR swab test more than two weeks after a COVID-19 infection does not necessarily mean that a person remains infectious. Previous research has not shown that close contacts are at risk of getting COVID-19 from people who continue to carry the virus.

Results from the CLARITY IBD study have shown that IBD patients treated with infliximab have lower antibody levels following COVID-19 infection and after a single dose of vaccine. Reassuringly, despite having lower antibody levels, patients treated with infliximab do not appear to be at greater risk of getting COVID-19 disease or becoming seriously unwell. However, it is not yet known whether use of infliximab, will cause some people to carry the virus for longer than expected. Understanding how long people carry the virus will help scientists and the government work out how to deal with the current and future outbreaks.

Why have I been asked to participate in this part of the study?

You have been invited to participate because you are already taking part in CLARITY IBD and have previously had a positive COVID-19 antibody or nose and throat swab test.

Do I have to take part?

It is up to you to decide whether to take part in this additional part of the CLARITY IBD study. If you do decide to take part, you will still be free to withdraw at any time and without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I decide to take part?

If you would like to take part, then please click on the link in the invitation email or text message or speak to a member of your local research team or the Exeter research team who are leading this project on 01392 406850. We will first ask you to give consent to participate. To do this an email or text message will be sent to you with a personalised link. You will then be asked to enter your surname and date of birth to confirm your identity before completing the e-consent form.

Participants will be asked to take a swab from their mouth (buccal swab) and complete a short questionnaire about persistent symptoms of COVID-19. The testing kit will be sent to your home, and you will be asked to do the test yourself. Taking the swab is quick, easy and comfortable, as it is

taken from the mouth and not the nose. You will be asked to return the swab in the post using the transport pack provided.

This swab will tell us whether you still carry COVID-19 virus, but it will not tell us if you are still infectious. If you have a positive test, you will be asked to carry out a repeat test every 4 weeks until you have a negative test, or we reach the end of the study.

As part of this study, we may also look at swab test results for coronavirus, which you have submitted in the past, or those which you may submit for another reason during the study period (e.g. if you have symptoms or are the contact of a case).

What will happen to my buccal swab?

The swab will be tested for the COVID-19 virus. If this is detected, further analysis will be undertaken to clarify if the virus is alive, and to look at its genetic code.

Will I be told my test results?

Yes, you will be told your results. You will be sent an email or text with an electronic link to get the result in the same way that you have been receiving your antibody results. Like all tests, this test is not perfect, so both “false positives” (the test result is positive, but you don’t have the infection) and “false negatives” (the test result is negative, but you do have the infection) are possible. We may report an “indeterminate result” and ask you to repeat the test if very low levels of virus are detected.

As required by law, we will share your swab test results and personal data (including your name, contact details, postcode and ethnicity) with Public Health England, Scotland or Wales depending on where you live.

What should I do if my buccal test result is positive?

If your buccal swab test is positive, we or a member of your local team will advise you further on any actions you may need to take, in line with current national guidance. NHS Test and Trace will also contact you.

If your buccal swab is positive, you do not need to self-isolate again if this is within 90 days of a first positive PCR test for which you self-isolated, and you have no symptoms of COVID-19. A second period of isolation is not needed because it is very unlikely you are still infectious. This advice is now supported by national legislation

If your buccal swab is positive, and your first positive test was more than 90 days ago, then you and your household will need to self-isolate for 10 days in line with national guidance <https://www.gov.uk/government/publications/covid-19-stay-at-home-guidance/stay-at-home-guidance-for-households-with-possible-coronavirus-covid-19-infection> This is because a positive test after 90 days may indicate a second coronavirus infection. You may be entitled to a one-off payment of £500 through the NHS Test and Trace Support Payment scheme if you are required to

stay at home and self-isolate or are the parent or guardian of a child who has been told to self-isolate.

Are there any benefits from taking part in this study?

The study will not benefit you directly, but your participation will help us understand whether drugs used in the treatment of IBD impact how long people carry the virus for.

Are there any disadvantages or risks from taking part?

The main disadvantage is the small chance that you and your household contacts may have to self-isolate again if you have a positive buccal test and this is more than 90 days from your first test. In addition, completing the swab test and posting it back to us may cause you some inconvenience.

What will happen to the results of the study?

At the end of the study, we will publish the results of this research. We will provide you with a copy of the publication if you request it. You will not be identifiable in this publication.

What will happen to my buccal swab?

We are required to store all positive swab tests after our experiments are completed. Negative buccal swab tests will be disposed.

If I participate will my personal medical information be kept confidential?

All information collected during this study will be kept safe and secure as detailed in the main CLARITY-IBD Participant Information Sheet (<https://www.clarityibd.org/patient-information-sheets>). As required by law, we will share your swab test results and personal data (including your name, contact details, postcode and ethnicity) with Public Health England, Scotland or Wales depending on where you live. However, your personal data will be removed before it is made available to members of the central research team. Data from the study will be kept for up to 5 years but the identifiable information, linking this to you, will be removed 12 months after the study has been finished. If you would like further information, please email rde-tr.clarityibd@nhs.net

What if I have a complaint or concerns about the study?

Whether or not you take part in the study, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during this study, the normal National Health Service complaints mechanisms would be available to you. Taking part in the study would not affect your legal rights.

Who is conducting the research?

This study is being carried out by a group of Gastroenterologists and scientists from the Royal Devon and Exeter Hospital and the University of Exeter. The central study office is at the Royal Devon and Exeter Hospital. The investigators are not being paid to carry out this work.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing, and dignity. This study has been reviewed and given favourable opinion by London-Surrey Borders Research Ethics Committee.

Who is organising and funding the research?

This study is funded by donations from several hospitals and pharmaceutical companies. It is supported by the National Institute for Health Research Clinical Research Network (NIHR CRN).

The sponsor of the research is the Royal Devon and Exeter NHS Foundation Trust. The sponsor may decide to stop the study at any time and if this happens the reasons will be explained to you. This will not affect your on-going clinical care. Any anonymised data that has been collected up until this time point will be used for analyses.

I have some further questions, who can I ask?

You can find further information at this website www.clarityibd.org and by contacting your local research nurse or a member of the central research team in Exeter on 01392 406850.