

CLARITY IBD

Impact of Biologic and Immunomodulatory Therapy on SARS-CoV-2
Infection and Immunity in Patients with Inflammatory Bowel Disease



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CLARITY NEWS

Participant Newsletter Issue 1

Jan 2021

Welcome to the first edition

Welcome to our first newsletter for people taking part in the CLARITY IBD study.

CLARITY NEWS will report monthly on our progress with the study and highlight early results as they emerge.

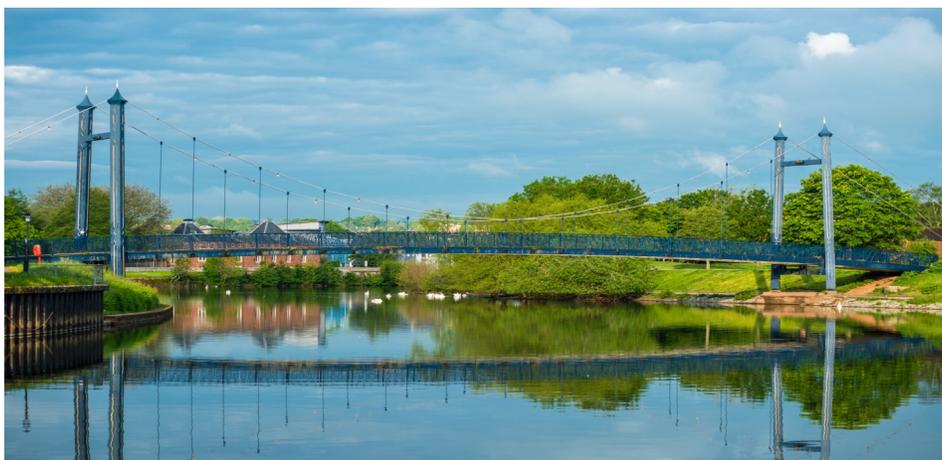
First of all we would like to say an enormous “thank you” for agreeing to take part in CLARITY IBD. On the 21st December 2020 we reached our target of 6,970 participants recruited from across the UK in 12 weeks. Every participant’s data is valuable to us and we sincerely hope you will all stick with us for the next 40 weeks.

With your help, we hope to be able to answer important questions about the impact of IBD drugs on COVID-19 infection and protective immunity. These questions can only be answered by studying lots of people and this requires a national effort!



Chief Investigators: Dr Tariq Ahmad and Dr Nick Powell

We wish you a Happy New Year!



Exeter Quayside

In This Issue

- What is the study all about?
- What does a positive COVID-19 antibody test mean?
- What do I need to do next for CLARITY IBD?



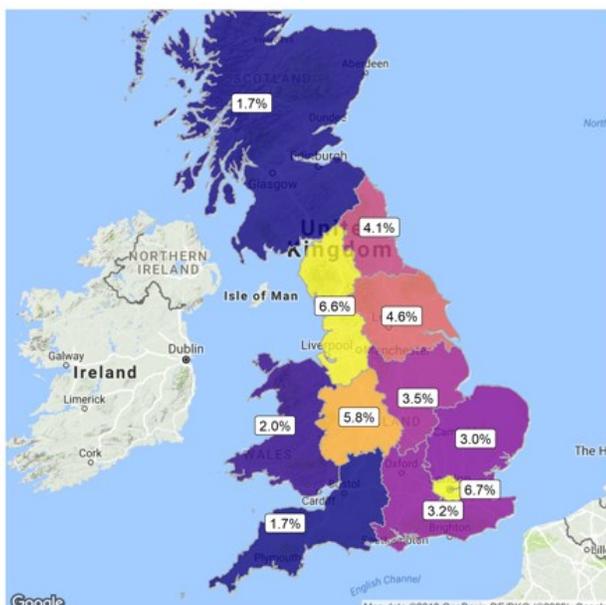
Patient using a tablet

What is the study all about?

Patients with IBD are often treated with biologic drugs, such as infliximab and vedolizumab. These drugs work by dampening down the immune system, but in so doing they may increase the risk of infections and prevent vaccines from working fully. Because COVID-19 is a new virus, we do not know if biologic drugs increase the risk of COVID-19 infection, although recent studies suggest the risk is likely to be low.

We need your help to understand more about COVID-19 risk

Every eight weeks we will send you a link to a questionnaire to complete. Four to six times during the study, we also need a small sample of blood to look for past evidence of COVID-19 infection. These antibody test results will be returned to you.



Regional seroprevalence

How is the study going?

The study opened in Exeter on the 22nd September 2020 and since then, more than 7,000 adults and children with IBD have been recruited from 92 UK hospitals.

150 patients joined the study every day!

On the 21st December 2020 we reached our target of 6,970 participants.



Hospitals participating in the CLARITY IBD study

How many participants have tested positive for COVID-19 antibodies?

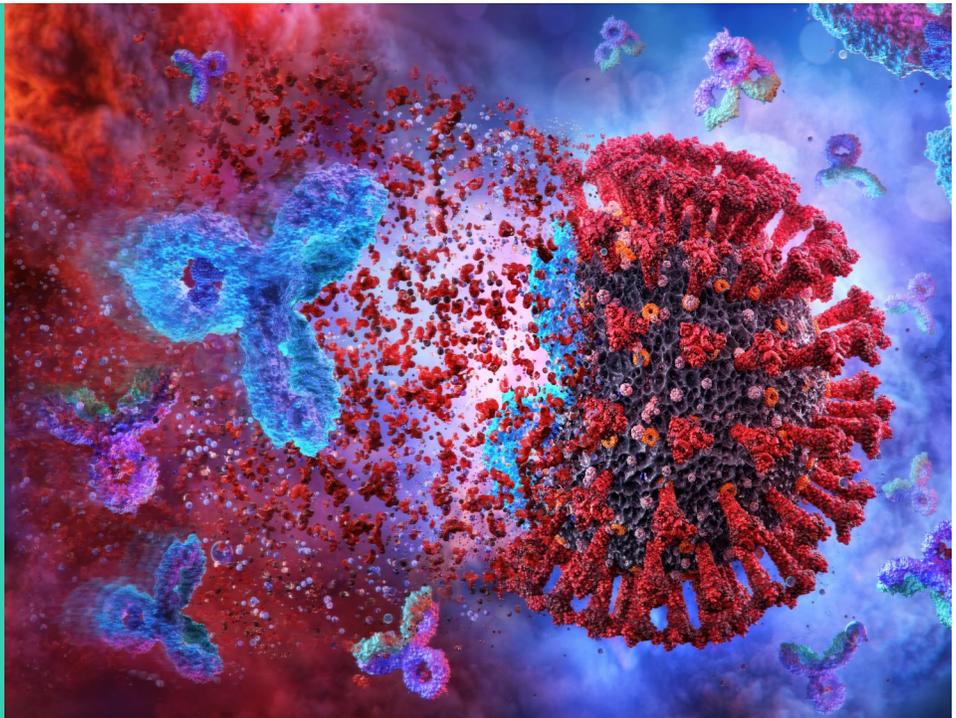
All participants have an antibody test at study visit 1. About 1 in 25 participants have had a positive test. The highest rates of positive antibody tests are seen in London and the North West. The lowest rates are seen in Scotland and the South West. As expected, patients who shielded during the national lockdown had the lowest rate of positive antibody tests.

The rate of positive tests observed in CLARITY IBD are similar to these reported in people without IBD.

We haven't yet analysed whether one drug or another impacts the rate of positive antibody tests

ANTIBODIES

WHAT ARE THEY, AND WHAT DO THEY MEAN?



Antibodies attacking the coronavirus

What are antibodies?

Antibodies are important proteins that help protect the body when you get an infection.

What are COVID-19 antibody tests?

An antibody test checks for antibodies in the blood and can tell you if it is likely you have had coronavirus before. An antibody test is different to a nasal swab test, which checks if you have the coronavirus now.

What does a positive COVID-19 antibody test mean?

A positive antibody test means it is likely that you have had coronavirus in the past. It is possible for you to have a positive antibody test without having had 'typical' symptoms of COVID-19, such as cough and fever.

What does a negative COVID-19 antibody test mean?

A negative antibody test means it is likely that you have not had coronavirus in the past. Depending on the timing of the antibody test, it is possible to have a negative antibody test despite having had a positive nasal swab test previously. Sometimes, antibodies are detectable for only a few weeks and then they go away.

Do not forget that having a positive antibody test may not mean that you are immune to coronavirus or that you cannot spread it to other people. Until we know more, you should remain careful.

COVID-19 vaccination has started. How will this affect the CLARITY IBD study?

The government has not yet indicated when patients with IBD will be offered vaccination. However, some study participants, who are also health care workers, or aged over 70 years, have already been vaccinated. From early January 2021, we will send you regular electronic links to submit details of any vaccine you choose to have.

If and when you have a vaccine, please click the link to submit the date and type of vaccine received.



When will I get my next COVID-19 antibody test?

If you had a positive COVID-19 antibody test at your first study visit *or* have ever had a positive RT-PCR nasal swab test *or* received a COVID-19 vaccine, you will have further antibody tests every 8 weeks. Otherwise your next antibody test will be at your third visit at week 16.

When should I complete my next questionnaire?

An electronic link or text will be sent to you every 8 weeks. If you do not have access to a computer or smart phone then you will be given a paper copy when you attend the hospital or your research site can ask you the questions over the telephone. Thank you for completing them.

Do check with your research or infusion team if you think you are due a test

Vaccine questionnaire (February 2021)

We want to hear your views on the new COVID-19 vaccines and whether you would be willing to receive one. You will be sent an invitation link. If you would like a paper copy, please contact your local research nurse.

Changes to the study (now approved)

1. Patients with a negative antibody test at visit 1 will be asked to have 3 further tests (rather than one) over the next 40 weeks. These results will be returned to you.
2. Patients who have had a positive RT-PCR nasal swab test before or during the study will have blood tests at every subsequent study visit.
3. Patients who have a COVID-19 vaccine will have blood tests at every subsequent study visit.

These changes are explained in the new patient information sheet.

We will ask you to confirm you have read the patient information sheet and are happy to have these extra tests when you complete your next questionnaire.

Please remind your local IBD teams when you attend the hospital if you think your next study blood test is due!

Contact Details

Contact your local research team if you have any questions about the study

Visit the study website:
www.clarityibd.org

Or contact the Exeter team
rde-tr.clarityibd@nhs.net