



# CLARITY NEWS

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

Since our last newsletter, spring has arrived and there seems to be some light at the end of the 'pandemic tunnel'. The UK vaccination programme has been hugely successful with over half of CLARITY IBD participants reporting that they have received their first vaccine injection.

The CLARITY IBD study has also been moving at a rapid pace. We have reported results from the first phase of the study looking at the impact of IBD drugs on COVID-19 infection and immunity. This has been published in the journal Gut and shared with researchers and patients all over the world. Again, we would like to thank you for your continued support of this study, without which we would not have been able to analyse and share these important results so quickly.

In this issue, we will explain the initial findings from our study, how it might impact you, and our future plans to understand if IBD drugs have an impact on response to the COVID-19 vaccination.

## In this issue:

- Initial results from the CLARITY IBD study
- Vaccination: what does this mean for you and for the CLARITY IBD study?
- Frequently asked questions on the CLARITY IBD study



The first CLARITY IBD results have been published in the UK medical journal Gut. This is an extraordinary achievement, having recruited the very first participant in October 2020. Importantly, this was only made possible with your help and commitment by completing the questionnaires and giving blood samples.

THANK YOU!

You can read the full publication online here:

<https://gut.bmj.com/content/early/2021/03/19/gutjnl-2021-324388>

## What are the results from the first paper?

- At entry to the study, similar rates of confirmed COVID-19 infections were seen in patients treated with infliximab and vedolizumab.
- Less than 1% of patients had been admitted to hospital with COVID-19 and the rates were no different in vedolizumab or infliximab treated patients
- However, people taking infliximab were less likely to have antibodies to the COVID-19 virus after infection than people taking vedolizumab. The lowest antibody levels were seen in people also taking azathioprine, mercaptopurine or methotrexate alongside their infliximab.

## What does this mean?

We don't yet know whether a weakened immune response in patients treated with infliximab means that these patients have an increased risk of further infection.

Protective immunity after infection involves more than just antibodies and it is likely that other parts of the immune system help people fight off the virus.

At the current time, we strongly recommend that patients continue to take their anti-TNF medicines and to have a vaccine as soon as this is offered.

## What does this mean for me?

**Should I stop or change my medication?** No. There is not enough evidence to recommend switching from infliximab to vedolizumab right now. Vedolizumab does not work for everyone, and so you may be risking a flare-up if you decide to try it when infliximab is already working well for you.

**Should I still get vaccinated?** Yes. We strongly recommend that you have the COVID-19 vaccine when offered, regardless of which medicine you take or if you have had coronavirus before.

**What if I don't make antibodies after vaccination?** Antibodies are not the only way your body can protect you from viruses. Even without vaccination, there is no evidence that people with Crohn's or Colitis are more at risk from coronavirus than the general population.

No vaccine is guaranteed to work for everyone. All adults in the UK are being offered the vaccine, meaning that you are less likely to come into contact with coronavirus. Plus some form of distancing, mask wearing and increased hygiene measures are still likely to be in place in the longer term. These measures are in place to protect the most vulnerable.



**Dr Nick Powell (Imperial College):**

"Although we clearly observed diminished antibody responses in patients taking infliximab, we haven't yet completed our investigation of T-cell and other protective immune responses against the virus.

I would expect that even in the presence of less efficient antibody production, infliximab-treated patients will mobilize some protective aspect of their immune system to protect themselves."



**Sarah Sleet (CEO of Crohn's & Colitis UK):**

"At this stage, the key message is that people with Crohn's and colitis should keep taking their medication to stay well, and to take the vaccine when offered. But we also need

research like this to continue. A huge number of people with Crohn's and colitis have had to content with the stresses of shielding and social distancing, and it's vital that this group is prioritized in research."



# VACCINATION AND ANTIBODIES

What does a positive 'N' COVID-19 antibody test mean?

The antibody test currently reported to you in the CLARITY study is a 'N' or nucleocapsid test. A positive 'N' antibody test means that it is likely that you have had COVID-19 in the past. It is possible for you to have a positive 'N' antibody test without ever having had 'typical' symptoms of COVID-19, such as a cough or fever.

What will my COVID-19 antibody test show after vaccination?

The 'N' antibody test currently reported to you in the CLARITY study does not detect antibodies made by your body following vaccination.

Therefore, you should not be concerned about a negative 'N' antibody test following vaccination.

To measure your antibody response to infection we are using a 'S' spike antibody test. At the current time we are not reporting these results to you because we don't yet know what these test results mean. Once we know more, we will make these results available to you. For now, we will continue to send you the 'N' antibody results.

What does a negative 'N' COVID-19 antibody test mean?

A negative "N" 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. Occasionally antibodies are detectable for only a few weeks and then disappear.



## CLARITY IBD

### Vaccine Response?

The second phase of the CLARITY IBD study is focussed on understanding how IBD medications affect response to the COVID-19 vaccination.

To help us understand what the results of these tests mean, it is really important for you to inform us when you have received a vaccine, to keep completing the questionnaires, and to have a blood sample at your next infusion.

We hope to share these results with you very shortly.

# Frequently Asked Questions

## I have stopped having infusions, how will this affect my participation in the CLARITY IBD study?

If you have stopped having infusions or have switched to a subcutaneous administration of your biologic drug, we really need you to stay in the study. Please keep completing the questionnaires every 8 weeks. You can either have your blood sample taken at routine blood monitoring appointments, or a home blood collection kit might be available to you. Please ask your IBD nurse or doctor about this.

## I have received the COVID-19 vaccine but I can't find the link to report this?

If you have received your vaccination, you can either record this in the questionnaire, or you can use the link that has been sent to you. If you can't find the link, please inform your local hospital team, or you can email [rde-tr.clarityIBD@nhs.net](mailto:rde-tr.clarityIBD@nhs.net) with the name of the hospital you attend, and we will forward the link to you.

## I haven't been receiving the link to the patient questionnaire?

If you are having difficulties accessing the questionnaire, or you have not received the link, please contact your local site or the Exeter team at [rde-tr.clarityibd@nhs.net](mailto:rde-tr.clarityibd@nhs.net). This could be due to an error in the email address or mobile number on the system which we would like to promptly correct.

## 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 smartphone or a computer, 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!

## I am moving out of the area, can I still stay in the CLARITY IBD study?

Yes! We are able to transfer you to one of the other 92 hospitals in Scotland, England and Wales who are participating. If you are moving to a different country, then it is not possible to collect blood samples, but you can continue to complete the questionnaire.



If you have a question, please email us at [rde-tr.clarityibd@nhs.net](mailto:rde-tr.clarityibd@nhs.net)

Remember if you change the email address or mobile number that you use to receive your results/questionnaire, this will need to be updated in the REDCAP system, so please inform your local research site, or email us.