



CLARITY NEWS

Special Edition COVID-19 VACCINATION



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- More published results from the CLARITY IBD study
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Welcome to the third newsletter for people taking part in the CLARITY IBD study.

This edition describes our new findings reporting the impact of IBD drugs on antibody responses to the Pfizer-BioNTech and Oxford-AstraZeneca COVID-19 vaccines. We will explain what these new findings mean for patients in the study and what questions still need to be answered.

Thank you for your continued support with this study, without this we would not have been able to analyse and share these important results so quickly.

The new data reports the impact of infliximab and vedolizumab on antibody responses following COVID-19 vaccination. These results have been published in the medical journal *Gut* and you can read the full article here:

<https://gut.bmj.com/content/early/2021/04/25/gutjnl-2021-324789>

What did the second CLARITY IBD paper investigate?

The research investigated antibody responses after a single dose of either the Pfizer/BioNTech or the Oxford/AstraZeneca COVID-19 vaccines in 865 people treated with infliximab, and 426 patients treated with vedolizumab.

We also looked at antibody responses after a single dose of vaccine in patients who had had a prior COVID-19 infection and in a small number of patients who had received two doses of COVID-19 vaccination. Antibody tests were carried out 3-10 weeks after a vaccine dose.

To test antibodies specific to vaccination we used a spike (S) antibody test. Up until now, we have not reported these results back to participants as we we don't yet know what these test results mean.



The current edition of *Gut* features Exeter Cathedral on the front cover and includes our first publication (highlighted in the last newsletter).

What do the results show?

- After a single dose of vaccine, only about one-third of participants (103 of 328) treated exclusively with infliximab generated adequate levels of antibodies to the virus for the vaccine to be considered effective.
- Antibody levels after a single dose of vaccine were reduced further in participants simultaneously taking infliximab and immunomodulator drugs, such as azathioprine or methotrexate.
- Reassuringly, however, in those participants who had previous COVID-19 infection or had a second dose, the antibody response was much stronger.
- The analysis also found evidence that antibody responses were lower in current smokers and participants aged 60 or older. Antibody responses were higher in non-white participants.



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What does this mean for me?

We strongly recommend that you get vaccinated at the first opportunity with either vaccine. Strong antibody responses are seen after two doses of vaccine in patients taking either vedolizumab or infliximab. After just a single dose of vaccine, patients treated with infliximab may not be completely protected from COVID-19. Therefore, if you are treated with infliximab, continue to practice enhanced social distancing until you receive your second dose.

Should I stop or change my medication?

No. Do not stop or switch your medication without talking to your IBD team. You might risk a flare-up.

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 previous COVID-19 infection.

What if I don't make antibodies after vaccination?

Don't worry. The antibodies are not the only way your immune system can protect you from viruses. T-cells are also important and are being studied in the next stage of the CLARITY IBD study. In addition, COVID-19 infection rates are rapidly falling in the UK as the population is vaccinated. However, it seems likely that additional booster vaccine doses may be offered in the Autumn 2021 to patients taking immunosuppressive medicines, such as infliximab and vedolizumab.

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

The 'N' antibody test currently reported to you in the CLARITY IBD 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.

Shortly, we will be seeking your opinion as to whether you would like to receive your 'S' 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.

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

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.

CCUK provides further information about IBD and COVID –19 vaccinations:
<https://crohnsandcolitis.org.uk/>

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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 with the name of the hospital you attend, and we will forward the link to you.

I haven't received 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. 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 hospital. Alternatively, 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.



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If you have a question, please email us at 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.