CLARITY IBD

Exeter IBD Research Group

Exeter IBD Pharmacogenetics Research Group
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Impact of Biologic and Immunomodulatory Therapy on SARS-CoV-2 Infection and Immunity in Patients with Inflammatory Bowel Disease

www.clarityibd.org

PARTICIPANT NEWSLETTER
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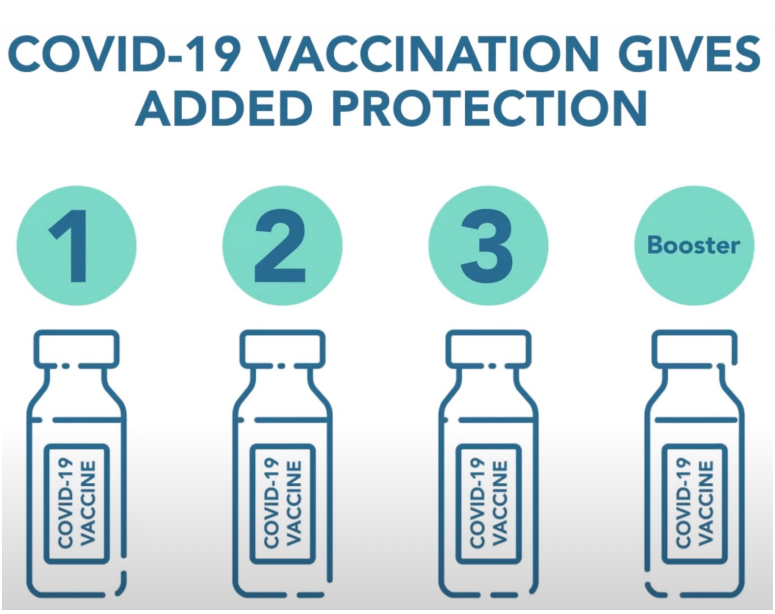
CLARITY NEWS

Welcome to CLARITY News. It has been almost 2 years since the start of the CLARITY IBD research study. Thanks to your help and support, we have gathered vital information to help us understand the impact of IBD medications on immune responses to the COVID-19 virus and vaccines. These results have informed UK and international government vaccine recommendations.



Sharing success

European Crohn's and Colitis Organisation - investigator initiated award
https://www.ecco-ibd.eu/abstracts-21/ecco-abstract-awards-2021.html

ECCO European Crohn's and Colitis Organisation

British Society of Gastroenterology and National Institute of Health and Care Research award - team making an outstanding contribution to portfolio studies
https://www.nihr.ac.uk/news/outstanding-gastroenterology-and-hepatology-medicine-research-leaders-commended/28082

bsg NIHR | National Institute for Health Research

In this edition of CLARITY newsletter, we report the latest results from CLARITY, future projects moving forwards, and share some of the lessons we have learnt from conducting a research study during a global pandemic.

In this issue:

RESULTS FOLLOWING A 3RD DOSE OF COVID-19 VACCINE IN PATIENTS WITH IBD

Study results have been published in two journals:

Nature Communications: https://www.nature.com/articles/s41467-022-28517-z

Gut: https://gut.bmj.com/content/early/2022/08/01/gutjnl-2022-327570

What did we investigate?

1. **Antibody responses following a 3rd dose of vaccine** (either the Pfizer/BioNTech or the Moderna COVID-19 vaccines) in 918 infliximab- and 442 vedolizumab-treated participants who did not have prior COVID-19 infection.

2. **Breakthrough infection and reinfection**: the number of participants who had a COVID-19 infection despite receiving the vaccine ('breakthrough infection') and the number of participants who developed COVID-19 infection at least twice ('reinfection').

3. **Hospitalisation from COVID-19 throughout the pandemic**

What did the results show?

- A third dose of a messenger RNA-based COVID-19 vaccine (either BNT162b2 (Pfizer-BioNTech) or mRNA-1273 (Moderna) substantially boosted COVID-19 antibody responses in patients receiving infliximab and vedolizumab treatment. However, participants treated with infliximab had antibody levels that were 5.5 times lower compared to vedolizumab-treated patients.

- COVID-19 infection after a third dose of COVID-19 vaccine occurred in approximately 15% of patients in the study, and most were due to the Omicron variant. Breakthrough infection was more common and occurred earlier in patients receiving infliximab treatment compared to patients receiving vedolizumab treatment.

- Re-infection occurred in 12.5% of patients and was mostly due to the Omicron variant.

- Hospitalisations remained uncommon, with 1.2% of patients requiring admission.

What does this mean for me?

1. **Vaccines continue to protect against severe illness, hospitalisations and death in infliximab and vedolizumab-treated patients with inflammatory bowel disease.**

2. **Infliximab (and other anti-TNFs, including adalimumab) are associated with attenuated antibody responses, breakthrough and re-infections.**

3. **Vaccination regimens for patients treated with anti-TNF therapy should include at least one dose of an mRNA vaccine (ie – Pfizer/BioNTech or Moderna), and boosters will need to be administered regularly.**

4. **In patients with active inflammatory bowel disease disease and COVID-19, treatment for inflammatory bowel disease should be prioritised and standard treatment guidelines should be followed.**

Future projects

Despite study visits concluding, we continue to analyse all the information that we have collected from participants to better understand the impact of specific treatments on COVID-19 infection and vaccination in patients with inflammatory bowel disease. We aim to understand:

1. Does infliximab drug level at the time of COVID-19 vaccination impact vaccine response?

2. How common is long COVID in patients with inflammatory bowel disease and how does it affect them?

Watch the latest video from the CLARITY IBD team explaining results from the study to date and what this means for patients with IBD:

https://www.youtube.com/watch?v=R67WUchmazA

Hear Prof. Ahmad talk about delivering the study during the pandemic here:

https://open.spotify.com/episode/2QvdnVoaTalA1dSogcrHaS

How we handle your data

The CLARITY IBD study closed on June 30th 2022. For the next 10 months, we will continue to investigate the impact of immunosuppressive and biologic drugs on COVID-19 vaccine response. To do this, we will continue to link the CLARITY study data with COVID-19 testing and vaccination information held by NHS Digital and the UK Health Security Agency. We will do this using your name, date of birth and NHS number. The study team at the Royal Devon and Exeter Hospital and these government bodies already hold these data, but the matching process ensures that the testing and vaccination data we share securely relates the correct participant in the CLARITY IBD study.

Twelve months after the study end date (June 30th 2022), your personal identifiable information which enables us to link the study data to you will be destroyed. The study data will then be anonymised and kept for an additional 4 years before being destroyed. Data will be destroyed safely in accordance with the GDPR and the Data Protection Act 2018 and the NHS Digital requirements, as set out under The Royal Devon University Healthcare NHS Foundation Trust's Data Sharing Framework Contract and Data Sharing Agreement with NHS Digital. This process was approved by an ethical committee that reviewed study.

If you have any concerns about the use of your data in this way, please contact the CLARITY IBD email: rde-tr.clarityibd@nhs.net

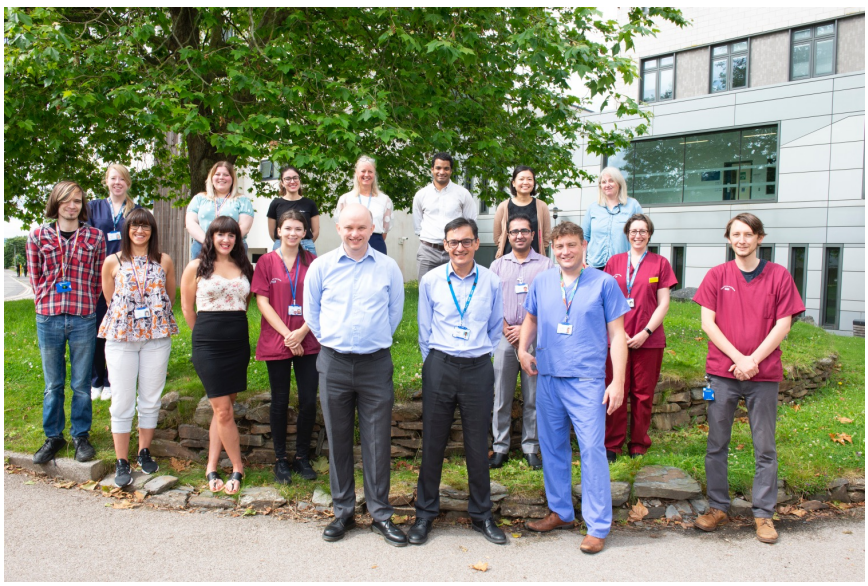
CROHN'S & COLITIS UK

CCUK provides further information about IBD and COVID-19 vaccinations, please visit https://crohnsandcolitis.org.uk/info-support/information-about-crohns-and-colitis/coronavirus-information

Thank you

From the CLARITY IBD team, **thank you** to patients and research staff from the 92 UK hospitals that have participated in the study.

The findings from the CLARITY IBD study have helped shape COVID-19 related clinical decisions and international policies to improve outcomes in patients receiving immunosuppressive therapy across a range of conditions.



CLARITY IBD team in Exeter

Nick Powell

Seb Shaji

>7000 patients
>400 research/IBD nurses
92 principle investigators

If you have a question, please email us at rde-tr.clarityibd@nhs.net or ring 07742909322

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