

Impact of biologic and immunomodulatory therapy on Sars-Cov-2 infection and immunity in patients with inflammatory bowel disease.

CLARITY (Extension)

Children information sheet (11-15 years)

Introduction

We are inviting you to continue to take part in research for another 24 weeks. Before you decide if you want to join in it's important to understand why the research is being done and what it will mean for you. So please read this leaflet carefully. Talk about it with your family, friends, doctor or nurse if you want to.

Please ask us if there is anything that is not clear or if you would like more information. Thank you for reading this.

Why are we doing this research?

We have shown that some medicines commonly used to treat inflammatory bowel disease stop coronavirus vaccines working properly. We want to continue this study to see what happens over a longer period of time.

Why have I been asked to take part?

You are being asked to take part because you are already part of the CLARITY IBD research study and you attend your local hospital for your biologic medication.

Do I have to take part?

No - not at all. It is completely up to you!
We only want people to take part if they want to. Just tell us if you don't.

Whatever you decide nobody will mind and it will not affect how you are looked after. If you decide to take part and then change your mind that is OK too. You can stop at any time, and you don't have to give a reason.

If you agree to take part you will be asked to write your name on an 'assent form'. This says that you understand the study and what will happen. You will be given your own copy of this form to keep as well as this information sheet.

What will happen to me if I take part and how long will it take?

If you take part, we will ask if it is OK to look at your medical records. We will also ask you some questions. We also need to take a blood sample. It will be taken at the same time as you have your normal blood samples taken, before your infusion. You will be asked if we can take the blood sample and if you can complete a questionnaire 3 times over 24 weeks. The questionnaire is short and takes about 5 minutes to complete.

Will it help me if I take part?

No, it won't. However, we hope that the information we get from this study may help other people in the future.

Is there anything to be worried about if I take part?

There are no risks from taking part.

What will happen to my blood sample?

Your blood sample will be given a code and sent to the Royal Devon and Exeter Hospital. Your name will not be given to anyone outside of your own hospital.

We will test your blood sample to see if you have had an infection caused by coronavirus, or if you have had a coronavirus vaccine, whether your body has produced antibodies to fight off coronavirus.

Your blood sample will be stored ~~for a long time~~ in a research bank and may be used for future research.

What will happen to the results of the study?

We hope to be able to write about the results of this study. We will be happy to provide you with a summary of this if you want. You will not be identifiable in this publication. You and your doctor will be told your blood test results.

Who has reviewed the study?

The study has been looked at by people who decided that it is okay for us to ask you to take part in this study. They are called the London-Surrey Borders Research Ethics Committee.

Who is organising and funding the study?

This study is being organised by doctors in Exeter, London and Hull. The study is helped by the National Institute for Health Research Clinical Research Network (NIHR CRN) and people in your local hospital.

Thank you for reading this. Please ask if you have any questions.

CLARITY (extension)

Children Assent Form

Child (or if unable, parent on their behalf) /young person to circle all they agree with please:

Have you read information (or had read to you) about this study?	YES	NO
Has somebody else explained this study to you?	YES	NO
Do you understand what this study is about?	YES	NO
Have you asked all the questions you want?	YES	NO
Have you had your questions answered in a way you understand?	YES	NO
Do you understand it's OK to stop taking part at any time?	YES	NO
Are you happy to begin this study?	YES	NO
Are you happy to continue with this study?	YES	NO

If any answers are 'no' or you **don't** want to take part, **don't** sign your name!

If you do want to take part, please write your name and today's date

Your name _____

Date _____

Your parent or guardian must write their name here too if they are happy for you to do the project

Print Name _____

Sign _____

Date _____

The researcher who explained this project to you needs to sign too:

Print Name _____

Sign _____

Date _____