

Participant Information for parents/carers and children aged 16-17 years

Study Title: Coronavirus infection in primary or secondary immunosuppressed children.

Chief Investigator: H. de Graaf

Principal investigators: H. de Graaf and S. N. Faust

Paediatric clinical teams involved: Rheumatology, Immunology and Infectious Diseases, Gastroenterology, Renal, Respiratory, Oncology, Neonatology, General Paediatrics

Sponsor ID: RHM CHI1061

IRAS ID: 281544

Information sheet – adults and young persons aged 16-17 years

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Website page:

Dear parent/carer and young person,

It is important to remember that if your child is unwell and needs medical care, you should follow the usual NHS clinical pathways.

Thank you for considering participating in this online study, in which we aim to monitor children and young people who have a condition that affects their immune system or are taking medication that affects their immune system during this coronavirus epidemic.

It is important to stress that the information currently available from the most severely affected countries suggests that these conditions and drugs do not seem to affect the response to coronavirus in children. However, we (and many of our families who have contacted us already) think it is sensible to collect data about what happens to children with immune problems. This will then enable us to give you more informed advice.

You and your child/young person are being invited to take part in this study. To help your family decide whether you would like your child to take part or not, it is important that you understand why the study is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide. If you need more information please discuss this with the consultant who takes care of your child or contact the study team.

What is the study about?

Some children are immunosuppressed or are being treated with drugs that affect their immune-system. **Most of these conditions and drugs have little effect on response to viral infections, and no serious coronavirus infections have been seen in immunosuppressed children so far from information currently available.** However, as COVID-19 (the new coronavirus) is a new virus there is no information yet about how children with immune problems or on immune-suppressant drugs will respond. A coronavirus epidemic is likely not going to be prevented in the UK and many parents are worried about the risk this may pose to their children and to their family as a whole.

We would like to keep a close eye on the children with immune problems and those who are taking drugs that affect their immune response. If we collect information from as many patients as possible, we can then give more accurate advice. This study will send you a weekly online questionnaire. We aim to collect information to see whether more children with immune problems are getting the coronavirus infection and how it affects them. We can then use this information to advise parents during a weekly update.

There is currently a national study looking at all people (adults and children) admitted to hospital with severe coronavirus infection. This is a separate study which you will be asked to take part in if your child/young person is admitted to hospital. We will share regular anonymised information and data (the study results) with colleagues across the UK and Europe, the NHS, Public Health England and the Department of Health. Information will be provided to parents from your regular clinical team in an easy to understand format as it becomes available.

Why have I and my child/young person been asked to participate and what will happen if I and my child/young person takes part?

If you or your child is less than 18 years old and has an immune deficiency or is on drugs that affect the immune system, you and your child have been asked to take part in this study. If you decide to take part, you will be asked to sign an informed consent on the next page of this website. After that there will be a short questionnaire about you or your child's condition, the medication he/she is on and how you want to be contacted. After that you will be asked to fill in a weekly online questionnaire asking questions about possible symptoms of coronavirus infection, time off school and use of medication. Links to the up to date national information and advice will be given to you with every questionnaire. If you cannot answer any questions please just leave them blank, but if possible, please provide as much information requested as possible.

We will send you the same questionnaire weekly until disease activity in the UK lessens, or you notify us you do not wish to take part. There will be an option to state "no symptoms" at the start of each questionnaire. After that we will put a summary of the results on this website. Participants will take part in the study for a maximum time of 1 year.

Are there any benefits to my child taking part and are there any risks?

There are no monetary (financial) benefits to taking part. The study may help the consultants caring for your child's condition and teams all over the UK and Europe to know how to better look after children like yours. The NHS, Public Health England and Dept of Health and Social Care will be kept informed of ongoing results. If any new information arises during this study which would change our advice to children with immune system problems then Public Health England and the local services will be informed in order to adjust local guidance. On the other hand, if no risk factors are found after substantial data-collection, the data collected might be reassuring to parents and their children. There is no risk of taking part in this study.

What data will be collected, will our data be kept confidential and will the NHS be given the result as soon as possible?

Personal identification will be collected but will be anonymised in all analysis and only visible by the study team and clinical consultants at University Hospital Southampton. Your child's participation and the information we collect about you and your child from the questionnaire will be kept strictly confidential.

Your mobile number and email address are required to send you the link to the questionnaire. Your child's date of birth, and details about their condition and their medications will be collected. If anything worrying is noted on a questionnaire the study team will liaise with the consultant who is caring for your child's condition to inform them. However, it is important to remember that if your child is unwell and needs medical care you should follow the usual NHS clinical pathways. The weblinks to Public Health England regional and national advice will be available on the front page of the study website when a questionnaire link is opened in case you need them urgently (or dial NHS 111).

Only members of the research team and responsible members of the University Hospital Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research complies with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your child's information, as a research participant, strictly confidential. This will ensure no data is traced back to your child following survey completion.

Do you and your child have to take part?

No, it is your decision whether you and your child/teenager may take part.

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason and without your child's routine care being affected. If you want your information to be removed from the study, we will do that if possible, otherwise the information you have given will be included in the final analysis. Once data has been anonymised for analysis it will no longer be possible to identify it and withdraw it from the study.

Where can I get more information?

If you have any questions please ask your clinical consultant, all of whom know about this study if you have been sent this questionnaire. If you would like to get information in writing please contact the NIHR Clinical Research Facility:

Email: uhs.recruitmentCRF@nhs.net

Telephone number: 023 8120 3853

If you have further questions please contact the Chief Investigator Dr. Hans de Graaf

Email: immunoCOVIDstudy@uhs.nhs.uk

What happens if there is a problem?

If you wish to complain may wish to contact:

PALS: 023 8120 6325 or patientsupportservices@uhs.nhs.uk

Who has reviewed the study?

The Leeds Research Ethics Committee has reviewed the study.

Data Protection Privacy Notice

The University Hospital Southampton conducts research to the highest standards of research integrity. When you agree to take part in a research study, we will use information about you in the

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ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. Personal data will be collected in this study. Only health related information will be collected as specified above. Please ask the research team if you have any questions or are unclear what data is being collected about your child.

Thank you for taking the time to read this information booklet