Information brochure for participationin medical-scientific study

The 'Coronavirus' in children

Official title:
Clinical and immunological characteristics of COVID-19 in pediatric patients (COPP-IMM study)

Preface

Dear ….

We want to ask you to participate in this study into the 'Coronavirus' (COVID-19). You received this letter because you are sick with the Coronavirus. Participation is voluntary. Will you participate? You can always change your mind and quit (at any time). Before you decide whether you participate in this study or not, it is important to have more information. Read this information letter. You can discuss it with your parents/guardians or other people you know if you want to.

Do you have any questions after reading this letter? You can discuss them with the researcher, Dr E.P. Buddingh; she knows a lot about the study. You can also send her an e-mail at copp@lumc.nl.
Do you want to discuss the study with a doctor who is not involved in it? Send an e-mail to Dr Meijer: c.r.meijer-boekel@lumc.nl. General information on participating in such research can be found on the website of the Dutch government: www.rijksoverheid.nl/mensenonderzoek

1. General information

This study is being conducted in the LUMC and other hospitals in The Netherlands. About 60 children and/or youth are participating. This study has been verified and checked by the Medical Ethical Committee of the LUMC (METC-LDD). They have approved of this study and have deemed it as causing hardly any strain. General information on the verification of research can be found on the following website: https://www.kindenonderzoek.nl/voor- ouders/wetenschappelijk-onderzoek/

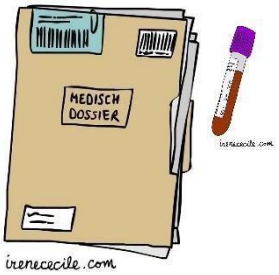
2. Why this study?

This study deals with the new illness caused by the 'Coronavirus'. This new virus causes adults, but also children, to become ill. We don't know exactly how it works yet. That is why we want to know how it affects you. For example, we want to know how long you were sick, what medication you received and how you got well again. We also want to know how the illness affected your daily life.

3. Background of the study

Since December 2019, a new virus has emerged, the Coronavirus, or SARS-CoV-2. This virus causes the disease COVID-19. Due to the spread of this virus, there was a large worldwide outbreak. Adults and children can become ill. It appears that children become ill less frequent and not as severe as adults. We do not yet understand why this is. We also do not yet know why some children become ill and others do not. With this study we hope to gain a better understanding of it.

4. What does participation in this study mean for you?



If you agree to participate in this study, then your participation will last for the duration of your stay in the hospital. You don't have to do anything extra to participate in the study. If you agree to participate, we will take an extra blood sample and we will send you a questionnaire.

Participation in the study consists of three parts:

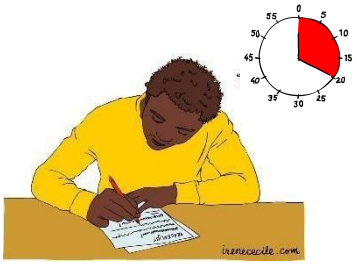
1. The doctors will note all information about your illness on the computer. This is your digital 'patient file'. We want to use the information in your patient file for our study. For example: the symptoms you suffered, your blood levels and what medication you are given.

   Were you admitted to the Intensive Care Unit (ICU)? Then we will ask separate permission to gain access to the information from the routine outpatient clinic visit after this ICU stay. That means the results from tests that doctors do to see how you are doing after having been admitted to the ICU. For example, your general health, ability to concentrate and an intelligence test.

   During your time in the hospital, maybe a blood sample has already been taken from you. Is there any left over from that? Then we would like to use that as well. We will ask separate permission.

2. We would also like to take an extra blood sample from you. We ask your permission to do this. We will try to do this at the same time it was already necessary to draw blood. If that is not possible, then we will ask you at a different time if we can take an extra blood sample. We will support you with this and we will make sure it won't bother you too much. We will ask separate permission.

3. 12 weeks after your visit or admittance to the hospital, we want to send you a questionnaire. This is a questionnaire about your complaints after you got home and how you are doing in general (for example: mood, sleep and contact with friends) The filling out of the questionnaire will take about 20-25 minutes.



We will ask separate permission for participation in follow-up research. Do you give permission? That means we can approach you in the future about follow-up research.

5 What is expected of you?

We really want the study to go well. That is why we are making the following agreements with you:

- If you give permission to participate in the study, we can collect theencoded data about your illness
- If you give permission for extra drawing of blood, we can draw an extra vial of blood from you.
- If you give permission for the filling out of a questionnaire, you will fill out the questionnaire we send you.
- If you wish to retreat from the study, you have to contact the researcher about this.

6 Possible inconveniences

You will experience no inconveniences during the collecting of your personal data. If the drawing of blood can be combined with the already required blood sampling for the benefit of your treatment, there will be no extra inconvenience. It could happen that this is not possible, and an blood draw is necessary. If so, we will make sure to support you so it causes you no/minimal inconvenience. For example, by using numbing cream. The filling out of the questionnaire which will be sent to your home, will take about
20-25 minutes, depending on your symptoms.

7 Possible advantages and disadvantages

Consider the advantages and disadvantages carefully before you decide whether you want to participate in this study. You yourself will have no benefit from participating in this research. But it will help us to gain more knowledge about the disease COVID-19 and the treatment against it. Possible disadvantages? It might be necessary to take an extra blood sample. You might find this scary,or it may hurt a little. Other than that, it will also cost you about 20 to 25 minutes to fill out the questionnaire.

If you do not want to participate or want to stop participation in the study.

You yourself decide whether you participate in the study or not. Participation is voluntary. If you decide not to participate, this will have no adverse consequences. Your treatment will continue as usual. You can always stop your participation, also during the study. You do not need to give a reason why you quit the study. You will have to inform the researcher right away. The data collected up to that point will be used in the study.

8 End of the study

Participation to the study will stop if:

- You are discharged from the hospital and the data from questionnaires andpotential follow- up research have been collected.
- You wish to stop participating in the study. You can do so at any moment. Inform the researcher right away. You do not need to give an explanation.
- The researcher thinks it is better for you to quit.
- One of the following institutes decides that the study needs to stop:

- the LUMC,
- the government, or
- the Medical-Ethical Committee who verifies the study.

The study is completed if enough data has been collected about the Coronavirus and its effects on children. The study is also finished if not enough test subjects participate in the study (for example because there are too few new Coronavirus infections in the Netherlands). After processing all the data, the researcher will inform you about the mostsignificant findings of the study. This will happen about a year after your participation.

9 What about privacy?

For the benefit of this study, the researchers will be collecting, using and store your personal information. It concerns, for instance, personal data like age, gender and results of your blood tests. Your personal data and body material (blood) are necessary to be able to answer the questions that are asked in this study and to be able to publish the results. We ask permission touse your personal data and body material.

Confidentiality of your personal data and body material.

To protect your privacy, the personal data and body material will be coded. Your name and other information that would identify you, are removed. Only with the key to the code can the information be traced back to you. The key to the code is safely stored at the local research facility (LUMC). In reports and publications regarding the study, the information cannot be traced back to you either.

Access to your personal data for verification

A few people receive access to your personal data at the research facility (LUMC). Also to the data which has not been coded. This is necessary for the purpose of verifying that the study has been conducted properly and is reliable. These following people can access the research results for the purpose of verification of the study:

- An inspector who works for the LUMC
- National controlling authorities, for example the Dept. of Health Inspection& Youth (Inspectie Gezondheidszorg en Jeugd- IGJ)

They keep your personal data confidential. We ask for your permission for this.

Retention period personal data and body material

The personal data we collect for this study needs to be kept at the research location (LUMC) for 15 years. Your body material is not destroyed after use. We save it and keep it at the LUMC. It is kept for 15 years to, as the study advances, be able to make new determinations with it that pertain to this study. As soon as it is no longer needed, we destroy the body material.

Saving and use of personal data and body material for other research

Your personal data and body material might be significant for other scientific research related to the Coronavirus and its effect on children. Do you agree with the use of it after this study? In

that case, your body material will be retained for 15 years at the LUMC. Do you not agree? Then you can still participate in the current study. You can express your preference on the consent form.

Revoke permission

You can revoke your permission at any time. Your personal data will no longer be used from that moment on. This is the case for this study and also for the retaining of data and its use in future research. The collected data up to the moment of the revoking of your permission, will still be used in this study. Your body material will be disposed of upon the revoking of your permission. If the body material has already been used for measurements, this data will still be used.

More information on your rights concerning the processing of personal data

You can find general information on your rights concerning the processing of personal data on the following website: https://autoriteitpersoonsgegevens.nl/.

For questions regarding your rights, or questions or complaints about the processing of your personal data, you can contact the entity responsible for processing your personal data. In this case that is the LUMC.
You can also contact the Data Protection Officer of the LUMC or the Authority Personal Data.
In **Appendix A** you can find all the contact information and the website of the LUMC.

Where can I find more information regarding this study?

Information regarding this study can be found on www.covidkids.nl. There is no personal data visible on this website. On this website you can find a summary of the results of this study (in the dashboard).

10 Insurance for test subjects

You don't run any additional risks by participating in this study. Therefor there is no need for the researcher to provide an extra insurance.

11 Compensation for participation

There is no compensation for participating in this study.

12 Do you have any questions?

For questions, you can contact the researcher. For independent advice on participation in his study, you can contact the independent physician Dr Meijer. She knows a lot about this study but is not involved in it. Do you have any complaints about this study? You can discuss this with the researcher or your attending physician. Do you prefer not to? Then you can address the Complaints Officer of the LUMC.
You can find all the information in **Appendix A**: Contact information.

13 Your decision

The consent form

Do you agree to participate? Then we ask you to sign the consent form.
You can also choose whether we can approach you for follow-up research. In the case of follow-up research, we might approach you with information about participation in this study. You can decide at that moment whether or not you want to participate in this follow-up study.

Wish to learn more?

Do you wish to learn more about medical research or about your rights? Check www.kindenonderzoek.nl
On this website you will also find the comic 'Anne en de Groeneneuzengriep' (Anna and the GreenNoseFlue") about research.
For this study, the preface and chapters 1, 2, 3, 6a, 9, 10, 11and 12, are relevant.

Do you wish to learn more about the Coronavirus and this study? You can check www.covidkids.nl

Appendices to this information

A. Contact information
B. Consent form

Appendix A: contact information

Contact information LUMC

Principal investigator:

Dr E.P. Buddingh
Leiden University Medical Centre, Willem-Alexander Children's hospital
e.p.buddingh@lumc.nl / copp@lumc.nl
Phone number: 071-5262824
www.covidkids.nl

Independent physician:

Drs. C. Meijer
Leiden University Medical Centre, Willem-Alexander Children's hospital
c.r.meijer-boekel@lumc.nl
Phone number: 071-5262824

Complaints:

For complaints you can turn to the Complaints Officer of the LUMC through e-mail: klachtenfunctionaris@lumc.nl. You can also call the Secretary of the Bureau of Quality and Patient Safety (071-5264646; during office hours). They will put you through to the acting Complaints Officer.

Privacy:

Data Protection Officer of the LUMC: If you have questions about the protection of your privacy you can contact the Data Protection Officer of the LUMC via infoavg@lumc.nl

For more information on your rights:

Contactgegevens LUMC
Albinusdreef 2
2333 ZA Leiden
Centraal telefoonnummer: (071) 526 91 11
Voor meer informatie over uw rechten zie de website van het LUMC
https://www.lumc.nl/12367/Deelnemers-wetenschappelijk-onderzoek/

Appendix B: Consent form for children of 16 years and older

The 'Coronavirus' in children

Clinical and immunological characteristics of COVID-19 in pediatric patients (COPP-IMM study)

- I have read the information letter for children of 16 years and older. I was also able to ask questions. My questions were answered satisfactory. I had enough time to decide whether I want to participate.

- I understand that participation is voluntary. I also know that I can decide at any moment to revoke my permission. I am not required to give a reason for that.

- I want to participate in the study and I give permission for my personal data to be used for the purpose as stated in the information letter.

- I give permission to the Health Inspection and inspectors on behalf of the initiator of the study (LUMC) to receive access to my medical files and my research data.

- I give permission to retain my research data for up to 15 years after the end of this study

I give permission to use data from my electronic patient file for the benefit of this study *(In case of a negative answer you won't be able to take part in this study)*	☐ Yes ☐ No
When applicable, I give permission for the use and storage of left-over material	☐ Yes ☐ No
I give permission for an extra drawing of blood for the benefit of this study	☐ Yes ☐ No
I give permission to retain my body material after this study for up to 15 years to use for follow-up study into COVID-19 as is stated in the information letter.	☐ Yes ☐ No
I give permission to retrieve information from the outpatient clinic after I was admitted to the ICU, including the results of the neuro-psychological tests.	☐ Yes ☐ No ☐ N/A
I give permission to send me, and perhaps my parents/guardians, a questionnaire: this will happen 12 weeks after my admittance /visit to the hospital.	☐ Yes ☐ No
I give permission to retain my personal data for 15 years and to use it for future research concerning COVID-19	☐ Yes ☐ No

I give permission to approach me again after this study for a follow- up study.	☐ Yes ☐ No

I agree to participate in this study.

My e-mail address is: _____

Name participant:

Signature: Date :_____/___/ ___

<u>This part is for the researcher:</u>

I hereby declare to have fully informed the test subject mentioned above, about the study concerned.

If, during the course of the study, information emerges that might impact the consent of the test subject, I will inform him or her timely

Name researcher (or their representative):
Signature: Date:_____/___/ ___

<*if applicable*> Additional information was given by:
Name:
Function:
Signature Date:_____/___/ ___

The test subject will be given a complete information letter, together with a signed version of the consent form.