Rijksinstituut voor Volksgezondheid en Milieu
Ministerie van Volksgezondheid, Welzijn en Sport

PIENTER Corona study

Immunity against SARS-CoV-2 in the Dutch population

In case the letter is send to your child (aged 2-16 years of age): please read this letter as an invitation for your child.

Introduction

Dear Sir/Madam,

You or your child is being asked to participate in a medical research study on the new coronavirus. Participation is voluntary. In order to participate your written consent is required. A few years ago you or your child participated in a large study to determine the protection against infectious diseases in the Dutch population: the PIENTER 3 study. In that study you informed us that the RIVM could ask you for your participation in a subsequent study, if needed. That moment is now.
Before you decide whether you want to participate in this study, we have important information for you about what the study involves. Please take your time to read this information and ask the investigator if you have any questions. You can also ask the independent expert mentioned at the end of this letter for additional information. You can also discuss it with your partner, friends or family. Further general information about participating in a medical research study can be found on the website of the Rijksoverheid: www.rijksoverheid.nl/mensenonderzoek.

1. General information

This study is being conducted by the National Institute for Public Health and the Environment (RIVM). The medical ethics committee MEC-U has approved the study. General information about medical ethical approval of medical research can be found on the website of the Rijksoverheid: www.rijksoverheid.nl/mensenonderzoek.

2. Purpose of the study

The aim of this study is to find out how the new Corona virus spreads among the general Dutch population. Persons who have been in contact with the virus will generate antibodies. You or your child have participated in the previous PIENTER 3 research in 2016/2017; the period before the outbreak of the new Corona virus. Through this new study we aim to determine, who has generated antibodies against the new virus and for that we will need a new blood sample. Measurements of antibodies over time will give important information about the spread of the virus and the possible development of group immunity.

With your participation in this new study, we are able to study the outbreak of the new coronavirus and cover the entire period before, during and after the outbreak. Anyone receiving this personal invitation can participate. We hope that you feel healthy, but possibly you currently have symptoms or maybe you have recently been ill. This doesn't matter, in either case you are welcome to participate, since it is important to get an overview of the general population.

3. Background of the study

In the Wuhan region in China an outbreak of a new coronavirus, also called SARS-CoV-2, started in December 2019. The virus can cause the COVID-19 disease. Most patients with this virus have fever and respiratory complaints. While most patients have relatively mild complaints, some patients have very severe complaints. The first COVID-19 patient in the Netherlands was diagnosed February 27th 2020. The virus has also spread in other countries in and outside Europe. Much is still unknown about this new coronavirus. Scientific research is needed to learn more about the virus, the disease spread and the development of group immunity.

4. What participation involves

If you participate, you are asked to fill in a questionnaire 3-6 times and collect a fingerprick blood sample from yourself (self-sampling) This will take place over a period of 1.5 years. Each time this will take about 30 minutes of your time (10 minutes for the questionnaire and a maximum of 20 minutes for the fingerprick). The number of times that we will approach you for the fingerprick and questionnaire will depend on the course of the corona epidemic.

The PIENTER Corona questionnaire will be completed at home and also the self-sampling of blood through the fingerprick can be done at home. Unlike the previous study that you participated in, everything will be done by yourself at home. So you don't have to come to a consultation hour at location. Based on our experience we know that the self-sampling of blood through a fingerprick works well. In case you have difficulties to complete the questionnaire on the website, you could ask a relative of friend for help. If for any reason it is impossible to complete the questionnaire online and you want to participate, then contact us for a paper questionnaire.

Would you like to participate?

- Please go to the PIETER Corona website and click on the application button ('aanmeld knop') www.rivm.nl/pienter-corona

In case you have further questions about this PIENTER Corona study, please send an e-mail to pienteronderzoek@rivm.nl.

Once we received your application we will send you a package. This package contains an informed consent form, as well as everything needed for the fingerprick blood collection. We kindly request that you fill in the questionnaire and perform the blood collection soon after arrival of the research package. In order to help you with the fingerprick collection, we added an instruction guide to the package. You can also find a video instruction on the website www.rivm.nl/pienter-corona.

Please send in the completed and signed informed consent form together with the small tube with the collected blood. Use the supplied plastic medical envelope. The plastic medical envelope is provided with a return address and can be send by regular post. It is important that you also fill in the PIENTER Corona questionnaire on the same day.

In addition to this you can also participate in the infection radar of the RIVM. For this you need to make an account on www.infectieradar.nl (currently, that website is down, once available we will inform you). On that website you can regularly record any health complaints that could be connected to the new corona virus, like fever or other colds, or report that you are healthy. This way we can compare the measurements in your blood to possible complaints.

5. What will be expected of you

For a good execution of the study, it is important that you follow the instructions listed below:

- send in the collected blood as well as the signed informed consent as soon as possible to the RIVM.
- complete the PIENTER Corona questionnaire on the same day.

It is important to contact the investigator

- in case you no longer want to participate in the study
- in case of any change in your contact details

6. Possible complaints

A fingerprick can hurt for a short moment. The amount of collected blood is 0.5 ml, which is about 10-20 drops. In case the first attempt fails, you can perform a second attempt using the second pricker. The choice is yours. In case of minor subjects always stop if they get upset.

In case of minors or incapacitated persons
Resistance of your child/the person you are representing
It may be that your child/the person you are representing resists during the study (does not cooperate) In that case please do not proceed with the fingerprick. (code of conduct
https://www.ccmo.nl/onderzoekers/publicaties/publicaties/2001/06/01/gedragscode-verzet-bijminderjarigen)

7. If you do not want to participate, or would like to stop participating in the study

Please consider the possible advantages and disadvantages before you decide to participate. You will not personally receive any advantage from taking part in this study. Your participation will contribute to more knowledge about the new corona virus and the COVID-19 disease.

Disadvantages of participation in the study may be

- It cost you some time (a maximum of 30 minutes)
- Some soreness in your finger

The study procedures are described in more detail under items 4, 5 and 6.

8. If you do not want to participate, or would like to stop participating in the study

Participation is voluntary. If you do not want to take part, you don't have to do anything.
If you do participate, you can always change your mind and stop, even during the study. You do not have to state why you are stopping. However, you should immediately inform the investigator. The data obtained thus far will be used for the study. If you like, the fingerprick material that was collected can be destroyed.

If there is any new information about the study that is important for you, the investigator will inform you of this. You will then be asked if you wish to continue your participation.

9. End of the study

Your participation in the study ends when

- all three to six fingerprick samples and questionnaires are completed and returned.
- you personally choose to stop
- the investigator deems it is better for you to stop
- the RIVM, the government or the assessing Medical Ethics Review Committee, decide to stop the study.

The entire study ends when all participants are finished. We will show the general outcomes of the study on the website.

10. Use and storage of your data and body material

For this study, your personal data and fingerprick material will be collected, used and stored. It involves information such as your name, address, date of birth and data about your health. For this study blood is required. The collection, use and storage of your data and your fingerprick material is required in order to answer the questions asked in this study and to be able to publish the results. We ask your consent for the use of your data and body material.

Confidentiality of your data and body material

To protect your privacy, your data and your body material will receive a code. Your name and other information that could directly identify you are therefore omitted. This information can only identify you with the key. The key to the code will be stored securely in the local research facility at the RIVM. The data and body material that is sent to the research laboratory and the researchers only contain a code, but not your name or other data that can identify you. In reports or publications about the study, the data will also not be identifiable.
We kindly ask you to give permission to combine health data that you submit to www.infectieradar.nl with the measurements and PIENTER Corona questionnaire. When combining we will also leave out any identifying information.

Access to your data for review

Some individuals may have full access to your data at the study site. Also to the data without a code. This is needed in order to check whether the study is performed

properly and reliably. Individuals who have access to your data for review are a controller that works for the RIVM, national and international regulatory authorities, for example, the Health Care Inspectorate and Youth. They will keep your data confidential. We ask your consent for this access.

Retention period of data and body material
Your data must be stored for a minimum of 20 years after the end of the study at the RIVM.
Your body material will not be destroyed immediately after use. It is stored in order to perform new assessments in the course of this study, related to this study or infection research. If you don't want this, you cannot participate to the study.

Withdrawal of consent
You can always withdraw your consent for the use of your personal data. This applies to this study and also for the storage and use for the future research. The study data that has been collected until the time you withdraw your consent will still be used in the study. Your body material will be destroyed after withdrawal of your consent. If measurements have already been taken with that body material, then that data will still be used.

More information about your rights concerning the processing of data
For general information about your rights concerning the processing of your personal data, please consult the website of the Dutch Data Protection Authority.

If you have any questions about your rights, please contact the person responsible for the processing of your personal data. For this study it is the Data Protection Officer for the RIVM, (see **Appendix A** for contact information, and website).

If you have any questions or complaints regarding the processing of your personal information, we recommend that you contact the study site. You can also contact the Data Protection Officer for the RIVM, (see **Appendix A** for contact information, and website).

Registration of the study
Information about this study is also included in a summary of medical research i.e. the Netherlands Trial Registry (http://www.trialregister.nl). No data that can be traced back to you is included. After the study, the website may contain a summary of the results of this study. You can find this study under PIENTER Corona.

11. Insurance for subjects

If you take part in the study, you will not incur any additional risks. The RIVM, therefore, is not required by the regulatory committee MEC-U to take out additional insurance.

12. No Compensation for participation

You will not be paid for participation in this study.

13. Do you have any questions?

If you have any questions, please contact researchers. If you would like independent advice about participation in this study, please get in touch with the independent doctor. She knows a lot about the study, but has nothing to do with this study.
If you have any complaints about the study, you can discuss this with the investigator or your regular doctor. If you would rather not do that, you can contact the RIVM. All data can be found in **Appendix A**: Contact information.

14. Signing of informed consent form

When you have had a sufficient reflection period, you can decide to participate in this study. If you consent, you will be asked to confirm this on the corresponding consent form, in writing (the form will be send to you in the package). With your written consent, you indicate that you have understood the information and agree to participate in the study.
Both you and the investigator will receive a signed version of this consent form.

For children below the age of 12 years, the parents or guardian must both sign the informed consent on behalf of the child. For children between 12-16 years of age both the parents/legal guardian and the child itself must sign the informed consent.

Best regards,

FRM van der Klis
Principal investigator PIENTER Corona
RIVM

16. Appendices with this information

A. Contact details

Appendix A: contact details

RIVM research team

You can ask questions to the RIVM research team.
Monday to Friday from 9:00-15:00 at telephone number: 030 – 274 32 99
Please specify that you participate in the PIENTER Corona study.
Or by e-mail: PIENTERonderzoek@rivm.nl

Independent person

Nicoline van der Maas (Physician with knowledge on infectious diseases)
Phone number: 030 274 7565

Complaints

For complaints you can always contact het RIVM research team (see above). If you don't want to discuss the complaint with the RIVM research team, you can contact the head of the department: Dr. Diana Wouters.
T: 030-274 2219 or 030-274 3119
You can also issue an official written complaint about the PIENTER Corona study to:

Digitally:	info@rivm.nl
In writing:	RIVM
	To the attention of the Director-General
	PO Box 1
	3720 BA Bilthoven

Please state clearly above the letter of e-mail that it involves a complaint. Also state the subject of your complaints and the name of the study. See also:
http://www.rivm.nl/Klacht

Data Protection Officer

The RIVM controls the personals information of this trial. You can contact the Data Protection Officer of VWS. For questions about the right application and compliance of the privacy law, or about issuing a complaint.

Digitally:	FG-VWS@minvws.nl
In writing:	Ministry of Health, Welfare and Sport
	Directie Bestuurlijke en Politieke Zaken
	PO Box 20350
	2500 EJ The Hague

More information on your rights for the processing of your personal data can be found at the website of the Autoriteit Persoonsgegevens (https://autoriteitpersoonsgegevens.nl/nl/onderwerpen/avg-nieuwe-europeseprivacywetgeving/controle-over-je-data).