Information for participants in medical-scientific research

Thrombosis Risk factors

Introduction

Dear Mr/Ms,

We ask you to participate in a medical scientific study. Participation is voluntary. However, your permission is required in order to participate. You are receiving this information because you may had a thrombosis (blood clot) in 2021 and visited your hospital for this reason. But it is also possible to participate if this is not the case.

This study will take place throughout the Netherlands and will be led by Leiden University Medical Centre (LUMC). Approximately ten thousand test subjects are expected to participate in this study.

This study has been reviewed and approved by the nWMO Review Committee in Leiden.

Before you decide whether you want to take part in this study, you will be given an explanation of what the study entails. Please read this information carefully and if you have any questions ask the researcher. You can also discuss it with your partner, friends or family.

1. Purpose of the study

Every year, 20,000 Dutch people develop thrombosis, a blood clot in the veins. It is important to study how a thrombosis occurs so that we can learn how to prevent people from getting thrombosis in the future. By asking many people with thrombosis questions about possible causes of thrombosis and comparing these with the answers from people without thrombosis, we learn more about how these blood clots form.

2. What participation means

For this survey, we will ask you to complete a questionnaire **once**. This can be done online, but you can also ask for a questionnaire on paper. It will take about 10 to 30 minutes to complete the questionnaire. In this questionnaire, we will ask you questions about diseases, medicines, and other possible causes of thrombosis. You can choose your own moment to fill in the questionnaire. You can take a break, all answers will be saved automatically. When you restart by clicking on the link in the email below, you will automatically continue with the questionnaire where you were left.

Finally, we ask you if we may use your personal data at Dutch Statistics (CBS). This requires your hospital to share your personal data with the researchers. This concerns your postcode and date of birth. If you give your permission, your personal data will be collected, used and saved for this study. You can also complete the questionnaire without your personal details being shared.

3. What is expected of you

In order to successfully participate in the study, it is important that you fill in and complete the questionnaire honestly.

It is important that you contact the investigator if:

- You have a question about questions in the questionnaire
- Your contact details change

4. Possible advantages and disadvantages

The risks involved in this study are virtually zero. It is important that you weigh up the possible pros and cons carefully before you decide to take part. A benefit of taking part in this study is that you will help doctors and researchers to understand thrombosis better. A disadvantage of participating in this study is that it will cost you time to complete the questionnaire.

5. If you do not wish to participate or wish to discontinue the study

The decision to participate in the study is yours. Participation is voluntary. If you decide not to take part, you do not have to do anything else. You also do not have to tell us why you do not want to take part.

If you do participate, you can always change your mind and stop, even during filling in the questionnaire. You do not have to say why you are stopping. The data collected up to that point will be used for the study.

6. End of the study

Your participation in the study stops if:

- You have completed the questionnaire.
- You choose to stop by yourself

7. Use and storage of your data

For this study, your personal data will be collected, used and stored if you have given your consent. This concerns your postcode and date of birth. The collection, use and storage of your data is necessary to answer the questions posed in this study and to publish the results. We ask you for your permission to use your data.

Confidentiality of your data

To protect your privacy, your data will be coded. Your name and other data that can directly identify you, are omitted. Only the key to the code can be used to trace the data back to you. The key to the code remains safely stored in the research institute. Reports and publications about the research will not allow your details to be traced either.

Accessing your data for verification

Some people can access all your data on the research site. Also to the data without a code. This is necessary in order to check that the research has been carried out properly and reliably. The person who has access to your

data for verification purposes is the data protection officer. They will keep your data confidential. We ask you to give us your permission to give access to this information by this person.

Data storage period

Your data must be kept for 15 years at the research site.

Storage and use of data

Your data may also be important for other scientific research in the field of thrombosis after this study has ended. For this purpose, your data will be kept for 15 years. You can indicate on the consent form whether or not you agree to this. If you do not agree, you can simply participate in the current study.

Withdrawal of consent

You can withdraw your consent to the use of your personal data at any time. This applies to this study and also to the retention and use for future research. The research data collected up to the moment you withdraw your consent will still be used in the research, unless you indicate you want your data destroyed. This study will be published in a scientific journal. In this publication there will be none of your personal details. The removal of your data will only be possible until the moment this paper is offered for publication.

More information on your rights regarding data processing

For general information about your rights in relation to the processing of your personal data, please consult the LUMC website (http://www.lumc.nl/over-het-lumc/privacy/) and the Authority for the Protection of Personal Data. Should you have any questions about your rights, please contact the party responsible for processing the personal data. For this study this is: the LUMC. See Appendix A for contact details.

If you have any questions or complaints about the processing of your personal data, we recommend that you first contact the research site. You can also contact the Data Protection Officer of the institution, see Appendix A for contact details, or the Dutch Data Protection Authority.

8. No compansation for participation

You will not receive any compensation for this examination. There are also no costs involved for you.

9. Do you have any questions or a complaint?

If you have any questions, please contact W.J. van Dijk (w.j.van_dijk@lumc.nl).

If you have any complaints about this study, you can discuss them with the researcher or your physician. If you prefer not to, you can contact the complaints officer. All details can be found in **Appendix A**: Contact details.

10. Signature of consent form

When you have had sufficient time to think about it, you will be asked to decide on participation in this study. If you give your consent, we will ask you to confirm this in the online or paper questionnaire. By giving your written or digital consent, you indicate that you have understood the information and that you agree to participate in the study. Both you and the researcher will receive a version of this consent form.

Thank you for your attention.

Annexes to this information

A. Contact details
B. Consent form (if not given digitally)

Appendix A: contact details

(Local) Principal Investigator

Name: A. van Hylckama Vlieg

Function: Assistant Professor

Contact details: a.van_hylckama_vlieg@lumc.nl

Reachability: working days

Complaints

If you have any complaints about the study, you may discuss them with the researcher or your physician. If you prefer not to do this, you can contact the LUMC complaints officer by e-mail: klachtenfunctionaris@lumc.nl. You can also call the secretariat of the Department of Quality and Patient Safety (071-5264646; during office hours). They will put you through to the complaints officer on duty.

More information on your rights regarding data processing

For general information about your rights in relation to the processing of your personal data, please consult the website of the Dutch Data Protection Authority (Autoriteit Persoonsgegevens). For questions or complaints about the use or processing of your data, or about your rights, please contact LUMC's Data Protection Officer (FG): infoavg@lumc.nl.

Contact details LUMC:

Albinusdreef 2

2333 ZA Leiden

Central phone number: (071) 526 91 11

For more information on your rights, please visit the LUMC website.

www.lumc.nl/over-het-lumc/privacy/

Appendix B: consent form for participant (if not digital consent)

Thrombosis risk factors

- I read the information letter. I could also ask questions. My questions were adequately answered. I had enough time to decide whether to participate.
- I know that participation is voluntary. I also know that I can decide at any time not to participate or to stop the study. I do not have to give a reason.
- For this study, we will ask you to complete one questionnaire.
- I consent to the collection and use of my questionnaire data to answer the research questions in this study. I also give permission for the coded analysis and publication of the results.
- I know that for the purposes of monitoring the study, some people may have access to all my data. These people are mentioned in this information letter. I give my consent for these people to have access to my data.
- I am 16 years or older and understand the English language sufficiently.

I □ **do**

□ **do not** give consent to the retention and use of my personal data for future research in the field of thrombosis.

I □ **do**

□ **do not** give consent to my hospital sharing my special personal data (i.e. my date of birth and postcode) for the purpose of retrieving my data from Dutch Statistics (CBS).

Name of test subject:

Signature Date : __ / __ / __

I certify that I have fully informed this subject about the research in question.

If any information becomes known during the study that could influence the subject's consent, I will inform him/her in a timely manner.

Name of investigator (or his representative):

Signature Date: __ / __ / __

< if applicable>.

Additional information has been provided by:

Name:

Function:

Signature Date: __ / __ / __

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* Cross out what does not apply.