# Subject Information for participation in study of cerebral venous thrombosis

Dear Sir / Madam,

We kindly ask you to participate in a medical scientific study. Participation is voluntary. Your written permission is required to participate. We approach you because you recently had a cerebral venous thrombosis. By means of this form we would like to ask you if we may use your data and store it (encrypted, not traceable to you) in a database for research. It concerns a registry only. No experimental drugs or treatments are given in the context of this research.

Before making your decision, it is important to know more about the research. Please read this information carefully and ask the researcher for an explanation if you have any questions. You may also discuss it with your partner, friends or family.

## 1. Purpose of the study

The Covid-19 vaccination and CVT study is a study on adults who have experienced a cerebral venous thrombosis after a Covid-19 vaccination. With this study we want to gain more knowledge about this rare disease. For example, we want to study who is at risk to develop cerebral venous thrombosis after Covid-19 vaccination, as well as how the disease can be recognized. The more people participate, the better the research can be conducted. The Medical Ethical Committee of the Amsterdam University Medical Center has waived the requirement of formal approval for this study.

## 2. Background of the study

Cerebral venous thrombosis occurs when a blood clot blocks the veins in the brain, preventing the blood from draining properly. The severity of cerebral venous thrombosis can vary greatly from person to person. Complaints that may occur include: headache, nausea, vomiting, reduced vision, epileptic seizures, neurological deficits such as paralysis on one side of the body, and in some cases a decreased consciousness. Recently, several persons have developed cerebral venous thrombosis after receiving a Covid-19 vaccine. This could be a very rare complication of the new vaccine. It is currently unknown who is at risk of this potential complication, and how it can best be recognized.

## 3. What participation means

This is an observational study, which means that we only collect data from tests and treatments that you receive because they are necessary because of your illness. These data come from your medical record in this hospital. If necessary for the registry, additional information may be requested from other hospitals or medical institutions where you are or have been receiving treatment. We ask your permission for this as well.

## 4. What are the possible advantages & disadvantages of participating in this registry?

There are no disadvantages or advantages to participating. There is no additional burden for you. Your participation in the registry will, however, contribute to the scientific research that is necessary to improve the diagnosis and treatment of cerebral venous thrombosis after Covid-19 vaccination. There are no costs or fees associated with participation.

## 5. If you do not want to participate or want to stop the investigation

You decide whether you want to make your data available for this study. Participation is voluntary. If you do not want to participate, you do not need to provide any reason for this. If you do not participate, you will simply receive the treatment that you would otherwise receive. If you do give consent, you can always change your mind and withdraw your previous consent.

## 6. Use and storage of your data

**Confidentiality of your data**

All data that is collected is treated confidentially. Your data is given a unique study code to protect your privacy. Data that directly relate to you personally (such as your name, date of birth or living address) are omitted from the database. Your data can only be traced back to you with the key to the code. This key remains safely stored in your hospital. The data cannot be traced back to you in reports and publications about the research either.

**Access your data for verification**

Access to the non-coded data is reserved for your treating healthcare provider(s) and the local investigator. In addition, in certain cases employees of competent authorities must be able to access this data, for example to check the accuracy of the data. For example, inspectors from the [Government Healthcare Inspectorate]. We ask you to give permission for this access.

**Retention period data**

After the study has ended, the data will be kept for 25 years at the research location in accordance with legal obligations.

**Withdraw consent**

You can always change your mind and decide to stop participation in this study. The data collected up to that time will be used for research, but will be cleared from any information that can be traced back to you (such as the study code).

**More information about your rights when processing data**

For general information about your rights when processing your personal data, you can consult the website of the [National Data Protection Authority]. If you have any questions or complaints about the processing of your personal data, we recommend that you first contact the researchers. You can also contact the Amsterdam University Medical Center's Data Protection Officer (contact details in Appendix A) or the [National Data Protection Authority].

## 7. Do you have any questions?

If you have any questions after reading this information, please contact your doctor or the local researcher. All details can be found in Appendix A: Contact details.

## 8. Signing of the consent form

When you have had sufficient time to reflect, you will be asked to decide whether you want to participate in this study. If you consent, we will ask you to confirm this in writing on the corresponding consent statement. By your written consent you indicate that you have understood the information and agree to participate in the study.

We kindly thank you for reading this information.

## 9. Appendices to this information

A. Contact details Amsterdam University Medical Center
B. Consent form(s)

## Appendix A: Contact details for Amsterdam University Medical Center

Principal investigator:
Dr. J. Coutinho, + 31 (0) 20 732 22 89

Coordinating investigator:
M. Sánchez van Kammen, + 31 (0) 20 566 35 47

Data Protection Officer:
S. van Hecke, + 31 (0) 6 24 38 33 94

## Appendix B : Subject Consent Form

Covid-19 vaccination and CVT study

- I have read the information letter. I have had the opportunity to ask questions. My questions have been sufficiently answered. I have had enough time to decide whether I want to participate.
- I know participation is voluntary. I also know that I can decide at any time not to participate or to stop participation in the study. I do not need to give a reason for this.
- I consent to requesting information from my GP/specialist(s) about my diagnosis and treatment of cerebral venous thrombosis.
- I consent to the collection and use of my data for answering the scientific question as described in the information letter.
- I consent to the sharing of my data in coded form (not traceable to me) with the Amsterdam University Medical Centre for the purpose of this study
- I know that some persons may have access to all of my data for the monitoring of the study. Those persons are listed in this information letter. I give permission for this access by these persons.
- I □ **do**

  □ **do not**

  give permission to approach me again after this study for any follow-up study.
- I want to participate in this investigation.

Name of subject:

Signature: Date : __ / __ / __

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