Information for clinical trial subjects concerning the participation in medical scientific research

Brain wave test in the ambulance for suspected stroke

Algorithm development through artificial intelligence for the triage of stroke patients in the ambulance with electroencephalography (AI-STROKE)

Introduction

Dear sir/madam,

We ask you to participate in medical scientific research. Participation is voluntary. To participate, we need your written consent. You receive this letter because you were recently brought to the hospital by ambulance with a suspected ischemic stroke. In the ambulance, an electroencephalography (also known as EEG or brain wave test) has already been performed for the purpose of this study. As it was in your best interest to be brought to the hospital to undergo diagnostic procedures (and possibly treatment) as soon as possible, your consent for performing a brain wave test was delayed until after admission. Because the brain wave test is not associated with any risks, the medical ethical committee gave permission to do this. Before you decide whether to participate further in this study you will get information about the study through this letter. Take the time to read this information thoroughly and ask any questions to the researcher. You can also consult the independent expert, who is named at the end of this letter, for additional information. Lastly, you can discuss the information with your partner, friends or family.

1. General information

This study was initiated by the Amsterdam UMC, location AMC (from here on: AMC). Multiple hospitals in North Holland participate in this study. The medical ethical committee of the AMC has approved this study. General information about obtaining approval for medical research can be found in the brochure “Medical scientific research”.

2. Aim of this study

The aim of this study is to develop an algorithm that can tell which patients have a large ischemic stroke in the ambulance, based on a brain wave test.

3. Study background

It is important to know in the ambulance which patients have a large ischemic stroke, so that these patients can be brought to one of the hospitals where treatment for large ischemic strokes is possible (this is not possible in every hospital). With this study, we want to develop an algorithm that can tell which patients have a large ischemic stroke in the ambulance, based on a brain wave test. In the future, these patients then can be brought directly to the right hospital.

4. What participation involves

Because the brain wave test needs to be performed quickly for this study, so that it does not delay diagnostic procedures (and possibly treatment), a brain wave test has already been performed in the ambulance. For this test, a sort of bathing cap with eight integrated electrodes was placed on your head. The electrodes were placed through the hair on the scalp and registered the brain wave activity. The brain wave test was performed only for the purpose of this study. If you do not want to participate in this study, the brain wave test data will be destroyed. If you do want to participate, we will use the data for this study. Other than that, we will ask you about your medical history and medication use and ask your treating physician about the results of the physical examination and scans that have been performed and about your diagnosis and treatment. We will also ask the ambulance service for data regarding the transport to the hospital. After that, your participation in this study has ended. The collected data will be saved by the investigator for 15 years. Participation in this study is voluntary. It does not influence your treatment in any way.

5. Possible advantages and disadvantages of participation

For you, there is no personal benefit of participation in this study. Your participation does contribute to what we know about early detection of stroke. The brain wave test does not have any known risks. Brain wave tests are regularly performed in standard medical practice. There are no side effects to the brain wave test. No X-radiation is used in a brain wave test. The equipment that we use conforms to the legislation and regulation of the European Union and is therefore CE-marked.

6. If you do not want to participate

As described above, the brain wave test has already been performed in the ambulance. We are asking for your permission to use these data for this study, and to collect additional data from yourself, your treating physician and the ambulance service (see chapter 4). You decide if you want to participate in this study. Participation is voluntary. You do not need to give a reason for declining participation. Participation does not influence your treatment in any way. If you decide not to participate in this study, this also will not influence your treatment in any way.

7. End of the study

As described before, the brain wave test has already been performed in the ambulance. If you decide to participate in this study, we will use the brain wave test data for this study and ask you, your treating physician and the ambulance service for additional information (see chapter 4: ‘What participation involves’). After that, your participation in this study ends. There are no follow up visits. The entire study ends only when all participants have finished. When the study has been completed and the data have been processed and analyzed, you can be informed by the investigator about the most important general findings. In the consent form, you can indicate if you want to know the general findings of this study.

8. Usage and storage of your data

Your personal data will be collected, used and stored for this study. This concerns data such as your name, address, date of birth, data about your health and the brain wave test data. The collection, use and storage of your data is required to answer the questions asked in this study and to publish the results. We ask your permission for the use of your data.

Confidentiality of your data

To protect your privacy, your data will be given a code. Your name and other information that can directly identify you will be omitted. Data can only be traced back to you with an encryption key. The encryption key remains safely stored in the local research institute. The data cannot be traced back to you in reports and publications about the study.

Access to your data for verification

Some people can access all your data at the research location, including the data without a code. This is necessary to check whether the study is being conducted in a good and reliable manner. Persons who have access to your data for review are the research staff of the AMC, the Healthcare and Youth Inspectorate and controllers working for the sponsor of the study. They will keep your data confidential. If you sign the informed consent form, you give permission for collection, storage and access of your personal and medical information. The investigators will save these data for 15 years.

Data sharing with external parties

We will share your coded data with commercial parties outside of the AMC. These parties do have a lot of experience with algorithm development and will help us developing an optimal algorithm for diagnosis of a large ischemic stroke. As mentioned in the paragraph ‘Confidentiality of your data’, your data can only be traced back to you with an encryption key. This encryption key will remain in the AMC and will not be shared with the external parties. External parties will therefore not be able to trace the data back to you.

Storage and use of data for other research

Your data may also be of importance for other scientific research in the field of stroke. Therefore, your data will be stored for 15 years. You can indicate on the consent form whether or not you agree with this. If you do not agree with this, you can still participate in the current study.

Information about unexpected findings

During this study, something may be found by chance that is not important to the study, but may be important to you. If this is important to your health, you will be informed by the investigator. You can then discuss with your general practitioner or specialist what needs to be done. You also consent to this.

Withdrawing consent

You can withdraw your consent to the use of your personal data for this study and/or future research at any time. If you only withdraw your consent for future research, the data will still be used for this study.

More information about your rights when processing data

For this study, the AMC is responsible for processing your personal data. For general information about your rights when processing your personal data, you can consult with the website of the Dutch Data Protection Authority (in Dutch: Autoriteit Persoonsgegevens).

If you have questions about your rights, please contact the research team. If you have questions or complaints about the processing of your personal data, we advise you to first contact the research team. You can also contact the Data Protection Officer of your hospital or the Dutch Data Protection Authority. You can find all contact information in appendix A: 'Contact information AMC'.

9. Insurance

This study is not associated with any risks for you. Therefore, the medical ethical committee has decided that no additional insurance needs to be taken out for this study.

10. Costs and financial compensation

Participation in this study does not cost you anything. You will not be paid for participation.

11. Questions

If you have any questions, please contact the research team. For objective council about participation in this study, you can contact the independent expert . He knows a lot about this study but is not involved in its execution. If you have any complaints, you can best contact the complaints committee of your hospital. You can find all contact information in appendix A: 'Contact information AMC'.

12. Signing the consent form

After having had sufficient time to deliberate, you will be asked to decide whether you wish to participate in this study. Should you give your consent, we will ask you to sign the written informed consent form. With your written consent you confirm that you have understood the information you received, and that you consent with both participation in this study and the use of and access to your data as mentioned in this letter. The signature form will be stored by the investigator. You will receive a copy of the consent form for your own administration.

13. Appendices

- Appendix A: Contact information AMC
- Appendix B: Informed consent form

Appendix A: Contact information AMC

Coordinating investigator
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Data Protection Officer AMC
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fg@amsterdamumc.nl

Dutch Data Protection Authority
0031 88 180 5250
www.autoriteitpersoonsgegevens.nl

Appendix B: informed consent form 'Algorithm development through artificial intelligence for the triage of stroke patients in the ambulance with electroencephalography (AI-STROKE)' study

Subject

- The aim of this study has been explained to me. I have read the information letter. I had the opportunity to ask questions. My questions have sufficiently been answered. I had enough time to deliberate if I wish to participate in this study.

- I know that participation is voluntary. I also know that I can decide at any moment to withdraw from this study. For this, I do not need to provide an explanation.

- I know that for verification of this study, some people can get access to my personal data. These people are listed in this information letter. I permit that these people have access to my data for verification purposes.

- I permit the collection and use of my data, for the goals as specified in the information letter.

- I know that my data will be stored for 15 years by the investigator, and will then be destroyed.

- I wish to participate in this study.

- I **do / do not (encircle your answer)** agree with use of my data for other research for 15 years.

- I **do / do not (encircle your answer)** agree with sharing my coded data with commercial parties outside of the AMC.

- I **do / do not (encircle your answer)** want to receive the study results on group level when the study has ended.

Name of subject: _____ Date of birth: ___/ ___ / _____

Signature: _____ Date: ___ / ___ / _____

Investigator / treating physician

- I hereby declare that I completely informed this participant about the study.

- If any information surfaces during the study that could influence the consent of the participant, I will inform the participant in a timely matter.

Name **investigator / treating physician (encircle what is applicable)**: _____

Signature: _____ Date: ___ / ___ / _____