Subject information for participation in medical research

New techniques for MRI

Official title:

Development and Validation of novel methods for Quantitative Magnetic Resonance Imaging of Tissue Properties

Introduction

Dear sir/madam:

We are asking you to take part in a medical research project.

Participation is voluntary, but to take part we do require your written consent.

Before you decide whether or not to take part in this research, we will explain to you what the research involves. Take your time to read the information thoroughly and ask the investigator to explain if you have any questions. You can also ask for extra information from the independent expert whose name is shown at the end of the letter. And of course you are welcome to discuss the research with your partner, friends or family.

1. General information

This research project has been set up by Delft University of Technology and is being carried out by Dr. Sebastian Weingärtner in HollandPTC (the Holland Proton Therapy Center).

The research has been approved by the Rotterdam Medical Ethics Review Committee. General information about participation in medical research and about how such research is reviewed can be found on the Dutch government website: https://www.government.nl/topics/medical-research.

2. Aim of the research

The aim of this research is to improve the reliability of new MRI techniques. By participating in this research you can help to improve the way we form images of organs in the body,

which may enable us to detect diseases at an earlier stage. The results of this research will be published in academic journals and made publicly available.

3. Background to the research

Diseases can have widely different effects on organs in the body. To detect diseases earlier, and to chart their progress, it is important that we continue to develop the present techniques. MRI already enables physicians to create images of organs without the need for surgery and without causing any damage to the body.

This study uses new MRI techniques in order to provide even more accurate imaging of organs. The research will enable us to improve the reliability and usability of these new techniques and it will hopefully ensure that diseases can be detected earlier.

4. What participation involves

If you participate, you will undergo MRI scanning which will take around 2 ½ hours.

Consent/determining physical suitability

In order to take part in the research you must first give your written consent. Without your written consent it is not possible for you to take part. You give your consent for your data to be collected and used for the research. You also consent to being informed by your primary care physician and/or the specialist treating you if there are unexpected findings that could be important to your health.

Once we have received your written consent, we will determine whether you may participate. For this, the investigator will ask you a number of questions about your medical history. This is important to ensure you do not have any contra-indications for undergoing MRI scanning.

Women who are pregnant and nursing mothers may not take part in this study.

Visits and measurements

To take part in the research you will need to make one visit to the Holland Proton Therapy Center. The whole procedure will take around 2 ½ hours.

The following will take place during your visit:

- We will review your medical history and ask you about any reasons why you may not be able to undergo an MRI scan.
- We will prepare you to enter the MRI room. This is because you cannot take any metal objects into the MRI room.

- We will conduct MRI scanning that will take a maximum of two hours.
  During the scanning we may:
  - Perform an electrocardiogram (ECG) to record your heartbeat.
  - Ask you to hold your breath for short periods of around 20 seconds. The investigator will help you with this by giving you instructions.
  - Ask you to perform simple tasks such as touching your fingers together.

Follow-up

Once we have completed the measurements, you will be asked if you are interested in participating in future studies. If you are interested we will keep you on the list of available volunteers. Otherwise we will remove you from this list.

5. What is expected of you

De MRI scanner is a relatively narrow tunnel that you have to lie in for around two hours. This makes it difficult for people who suffer from claustrophobia to take part in this research. The MRI scanner is also very noisy, although we will provide you with earplugs to dampen the sound. If you decide not to participate in the research, this will not have any negative consequences for any future treatment you may receive in Holland PTC or any other hospital.

6. Possible adverse effects and other discomforts

Undergoing an MRI examination is harmless and no adverse effects are known for MRI.

The following discomforts occur frequently (1 in 10 people or more):

- Exposure to loud clicking sounds during the scanning. We will provide you with ear protection to dampen the sound.

The following discomforts may occur, but are less common:

- Temporary, light warming of body parts.

7. Possible benefits and risks

It is important that you weigh up the possible benefits and risks before you decide whether to take part. You will not directly benefit yourself from participating in this research. However, your participation may contribute to more knowledge on diagnosing a range of heart and brain disorders. Risks associated with participating in this research are described above in points 4, 5 and 6.

Participating in the research will cost you some time.

8. If you do not wish to participate, or you wish to stop your participation in the research

It is entirely up to you whether you decide to participate in the research or not. Participation is voluntary.

If you do participate, you are free to reconsider and stop at any time, even during the examination. You do not have to give your reason for stopping. However, you must report this to the investigator right away. Even if you decide to stop before the end of the research, you will still receive remuneration for your participation. The data that has been collected up until then will be used for the research, although you may also request that your data no longer be used and be destroyed.

If new information about the research becomes available that is important for you to know, the investigator will tell you and you will be asked if you wish to continue to take part.

9. End of the research project

Your participation in the research project will cease when

- the visit described under point 4 is over
- you decide to stop of your own accord

The entire research project is over once all of the participants are finished.

10. Processing and storage of your data

For this research project, your personal data will be collected, processed and stored. This data includes your name, address, date of birth and information about your health. It is necessary to collect, process and store your data in order to answer the questions that are asked in the research and to be able to publish the results. We ask for your consent to your data being processed.

The privacy of your data

To protect the privacy of your data, your name and other data that could be used to personally identify you will be replaced by a code. Tracing the data back to you requires the key to the code. The key to the code is stored safely at Delft University of Technology and may only be accessed by the investigators who are directly involved in this research. All digitally stored data contain only the code and not your name or any other data that could be

used to personally identify you. Nor can the data be traced back to you in any reports and publications about the research.

Access to your data for verification

Some people at the research site may have access to all your data, including the data without a code. This is necessary to be able to verify that the research has been carried out properly and reliably. The people who can access your data for verification purposes are: the committee appointed to monitor the safety of the research and a controller who works for Delft University of Technology. They will maintain the confidentiality of your data. We ask for your consent to this access to your data.

Time limit for storing data

Your personal data must be stored for 15 years at the research site and 15 years at the client's location.

Storage and use of your data for other research

Once this research is completed, your data may be of importance for other scientific research in the field of MRI scanning and analysis. This is why your data will be stored for 15 years. On the consent form you can indicate whether or not you consent to this. If you do not consent to this, you can still participate in the present research project and your data will only be used for this purpose.

Information concerning unexpected findings

The data collected for this research are not intended for diagnostic purposes. Your images will not be systematically screened for abnormalities by a radiologist.

However, during the course of the research, something may be found by accident that could be of importance for your health. If this is the case, you will be informed of this by a radiologist. You can then discuss with your primary care physician or specialist what further action should be taken. You also give your consent for this.

Withdrawal of consent

You may withdraw your consent to the use of your personal data at any time. This applies to the current research as well as to the storage and use of your data for any future research. The research data collected up until the moment that you withdraw your consent will still be

used in the research. However, you may request that your data no longer be used and that it be destroyed.

More information about your rights with regard to the processing of personal data

For general information regarding your rights regarding the processing of your personal data, please refer to the website of the Dutch Data Protection Authority: https://autoriteitpersoonsgegevens.nl/

If you have any questions about your rights, please contact the institution responsible for the processing of your personal data. For this research this is:

Delft University of Technology: See Appendix A for the contact details.

If you have any questions or complaints concerning the processing of your personal data, we advise you to first contact the principal investigator, Sebastian Weingärtner. You may also contact the Data Protection Officer of the institution (see contact details in Appendix A) or the Dutch Data Protection Authority.

11. Insurance for subjects

As there are no extra risks associated with your participation in this research project, the investigator is not required to take out extra insurance by the review committee.

12. Remuneration for participation

If you take part in this research project you will receive a remuneration to cover your travel and parking expenses of a total of € 35 per visit. This sum must be declared as income for tax purposes.

13. Any questions?

Please contact the investigator if you have any questions. Please contact the independent expert if you would like independent advice about participation in this research. The independent expert knows a lot about the research but is not involved in it in any way.

If you have any complaints regarding the research projects, you can discuss these with the investigator or with the physician treating you. If you would rather not do this, you can also contact the complaints officer. You can find all the contact details in **Appendix A**: Contact details.

14. Signing the informed consent form

After you have had sufficient time to consider, you will be asked to decide whether to participate in this research project. If you give your consent, we will ask you to confirm this in writing on the accompanying informed consent form. By giving your written consent you indicate that you have understood the information and you consent to participation in the research.

Both you and the investigator will receive a signed copy of this declaration of consent.

Thank you for your attention.

Kind regards,
Dr. Sebastian Weingärtner

15. Appendices to this information

A. Contact details

B. Overview of measurements

C. Informed Consent Form

Appendix A: contact details for Delft University of Technology

Principal investigator:

Dr. Sebastian Weingärtner

Assistant Professor, Department of Imaging Physics

Faculty of Applied Sciences

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2628 CJ Delft

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Investigator at the local research institute (HollandPTC):

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Independent expert:

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Telephone: +31 10 7030797

Complaints:

If you have any complaints, please report this to the investigator. If you are unhappy about the way the research is being conducted and you wish to submit a complaint, you can report this to the TU Delft Integrity Office: integrity@tudelft.nl

Institution Data Protection Officer:

J. van Leeuwen, MSc, LLM, Certified Information Privacy Professional/Europe

Legal Services Department, Legal Affairs

Delft University of Technology
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2628 CJ Delft

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Appendix B: Overview of measurements

Duration	Steps
10 - 15 minutes	*Prior examination:* We will review your medical history and ask you about any reasons why you may not be able to undergo an MRI scan.
10 - 15 minutes	*Preparation:* Preparation for entering the MRI scanner. Changing into hospital gown. An investigator may attach electrodes to your body to be able to perform an ECG during the scanning.
1 ½ - 2 hours	*MRI scans:* various scans will be made. It is important that you remain completely still while the scans are being carried out. You may be asked to hold your breath for short periods lasting around 20 seconds. The investigator will help you with this by giving you instructions. You may be asked to perform simple tasks during the scan, such as touching your fingers together.

Appendix C: Informed Consent Form for subjects

New techniques for MRI

- I have read the information letter and have been able to ask questions. My questions have been answered satisfactorily. I have been given sufficient time to decide whether I want to participate.
- I know that participation is voluntary. I also know that at any time I can decide not to take part and to cease my participation in the research project. I do not have to give a reason for this.
- I give my consent for my data and the MRI scans to be collected and processed for the purpose of answering the research question in this research project.
- I know that some people will have access to all of my data for the purpose of verifying the research. I consent to my data being accessed by the people stated in the information letter.
- I consent to my primary care physician and/or the specialist who is treating me being informed if there are any unexpected findings that could be of importance for my health.
- I □ **do**

  □ **do not**

  give consent for my personal data to be stored for a longer term and to be used for future research in the field of MRI scanning technology.
- I wish to participate in this research project.

Name of subject:

Signature: Date: __ / __ / __

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

If during the course of the research any information becomes available that could affect the consent of the subject, I will inform them of this promptly.

Name of investigator (or representative of the investigator):

Signature: Datum: __ / __ / __

The subject is provided with the full information letter, together with a signed copy of the informed consent form.