Subject information for participation to medical scientific research

Feasibility of OCT fort he middle ear

Official title: Feasibility of middle ear imaging with OCT

Introduction

Dear Sir/Madam,

With this information letter we would like to ask you if you would like to participate in medical research. Participation is voluntary. You are receiving this letter because you have complaints related to the middle ear.
Here you can read about the research involved, what it means for you, and what the advantages and disadvantages are. It's a lot of information. Would you like to read through the information and decide if you want to participate? If you want to participate, you can fill in the form that you can find in Appendix C.

Ask your questions

With the information in this letter, you can make decisions. Besides that, we advise you to do the following:
- Ask questions to the investigator who provides you with this information.
- Talk to your partner, family members or friends about this investigation.
- Read information at www.rijksoverheid.nl/mensenonderzoek.

1. General information

Erasmus MC established this study in accordance with Acoustic Insight BV. Further on, Erasmus MC will be announced as ‘client’. Investigators who can be doctors, researchers or research nurses, conduct the study at the Erasmus MC in Rotterdam. Acoustic Insight BV pays this study and provides the required equipment.

For this study 100 participants are required.

The medical-ethical review committee of the Erasmus MC has approved this study.

2. What is the purpose of the study?

In this study, we look at how well the structure of the middle ear can be visualized with Aurisvue, a new device. It is also being investigated how well the function of the middle ear can be measured with this device. Finally, the potential clinical value of Aurisvue is assessed by comparing the measurements with other clinical data, such as specialist judgment or CT scans.

3. Wat is the background of the study?

The ear consists of the outer ear (pinna and ear canal), the middle ear (tympanic membrane, ossicles and tympanic cavity) and the inner ear (balance organ and cochlea). Problems with the middle ear, often inflammation, cause complaints such as pain or hearing loss. In order to investigate these complaints and to initiate treatment where necessary, it is important that the doctor can take a good look at the middle ear (especially the eardrum and the ossicles). An otoscope is now usually used for this and, if necessary, CT scans. However, an otoscope can only look at the eardrum from the outside and does not allow the doctor to look into the middle ear. This is possible with CT, but these are taxing due to the ionizing radiation and no small details can be seen with this.Optical coherence tomography (OCT) is an imaging technique that uses light. Because part of the light passes through the thin eardrum, it can also be used to see into the middle ear. In addition, OCT also allows very small details (down to a hundredth of a millimeter) to be viewed. Also, the function of the middle ear can be evaluated by measuring the vibrations of the eardrum and the ossicles.
OCT has made huge strides in ophthalmology over the past twenty years and has now become an integral part of clinical ophthalmic practice. For applications in the ear, there are currently no devices on the market with which OCT images are made. With this research we want to see what OCT can mean for ear surgery.

4. How does the study run?

How much time does the study take?
Are you participating in the research? In that case, this will not take longer in total than the period that you are under the treatment or monitoring of your specialist.

Step 1: are you fit to participate?
We first want to know if you are suitable to participate. That is why the researcher will first look at your medical history to determine whether there is a suspected middle ear disorder.

Step 2: studies and measurements
For the examination it is necessary that you are measured one or more times with the Aurisvue during your regular care process. During these measurements, for which you may have to travel extra to Erasmus MC, an attempt is made to visualize the middle ear as accurately as possible; this takes about 10 minutes. After the study you will be asked about your experiences with Aurisvue.
You do not need to undergo any other additional examinations or measurements for this examination, but you may have to come to Erasmus MC for the examination with Aurisvue.

What is different compared to standard care?
If you participate in this study, you will receive the same care as if you did not participate. The only difference is that the doctor will take OCT measurements in your ear or ears with

Aurisvue one or more times. These measurements are additional but will not change the care you receive

5. What appointments do we make?

We want the investigation to go well. There are no special restrictions or rules of life for this research. We do ask that you travel to Erasmus MC on the day of the Aurisvue measurements, even if this does not coincide with a regular visit to the hospital.

6. Which adverse events or burden can you expect?

There are no known or expected side effects or adverse effects when using OCT for middle ear imaging. However, you may experience discomfort because the tip of the device is pushed into the ear canal. This may be sensitive, similar to a normal otoscopic examination. The examination with the Aurisvue may take a little longer than the usual measurements with an otoscope.

OCT-metingen with the Aurisvue might bring some discomfort we don’t yet know.

7. What advances and disadvances will the study bring?

Participating in the study may have advantages and disadvantages. We list them below. Think about this carefully, and talk about it with others.

If you participate in this study, it does not mean that your complaints can be solved faster or better. But with your participation you help the researchers to gain more insight into the possibilities for improving the diagnosis and treatment of middle ear problems.

Participation in this study can involve the following drawbacks:

- You can suffer from the measurements during the study when your ears are sensitive because of your ear complaints, as described in paragraph 6.
- Participation in this study will cost you extra time (approximately 10 minutes per visit) an you possibly have to take an extra visit to the Erasmus MC.

It is possible that during the OCT examination something is discovered by chance that is not directly relevant to the study but is important for your health or that of your family members. In this case, your own GP or specialist will discuss with you what needs to be done next. The costs of this are covered by your own health insurance.

Do you choose not to participate?

You decide whether you want to participate in the study. Don't want to participate? Then you will receive the usual care for your complaints. Your doctor can tell you more about the treatment options available. And about its pros and cons.

8. When does the study end?

The researcher will let you know if there is new information about the study that is important to you. The researcher will then ask you whether you will continue to participate.

In the following situation the study will end for you:

- When all examinations are done.

When you want to cease the study. You can do that at every occasion. Report this immediately to the researcher. You do not have to say why you are stopping. You will also receive the usual treatment for your middle ear complaints.

- Report this immediately to the researcher. You do not have to say why you are stopping. You will also receive the usual treatment for your middle ear complaints.
- The investigator decides that it is better for you to quit.
- One of the following parties decides that the study must be stopped:
    - Erasmus MC,
    - The government, or
    - the medical-ethical commission that looks after the study.

What happens when you quit with the study?
The researchers use the data (like OCT-images) that have been collected until the moment you stop.

9. What happens after the study?

Do you receive the results of the study?
About 3 months after participation the researcher will let you know the most important outcome of the study.

10. What do we do with your data?

Do you participate with this study? Then you agree to collect, use and save your data.

What data do we store?
We store the following data:
- your name
- your sex
- your e-mail address
- your date of birth
- data concerning your health
- (medical) data that we collect during the study

Why do we collect, use and store your data?

We collect, use and store your data to answer the questions of this survey and to publish the results. In addition, the data and results will be used to improve Aurisvue and to set up follow-up research into OCT for middle ear complaints

How do we respect your privacy?

To protect your privacy, we give your data a code. We only put this code on all your data. We keep the key of the code in a secure place in the Erasmus MC in Rotterdam. When we process your data, we always use only that code. Also in reports and publications about the investigation, no one can recall that it was about you.

The encrypted data is shared with Acoustic Insight BV. They do not have access to the key of the code and can therefore not trace back that the encrypted data relates to you. The shared data can also be used by Acoustic Insight for the product development and marketing of Aurisvue.

Who can view your data?

Some people can view your name and other personal information without a code. These are people who check whether the researchers are conducting the research properly and reliably. These persons can access your data:

- Members of the committee that monitors the safety of the investigation.
- An inspector appointed by Erasmus MC.
- National and international supervisory authorities. For example, the Health and Youth Care Inspectorate.

These persons keep your data secret. We ask you to give permission for this access

For how long do we store your data?

We store your data for 15 jaar in the Erasmus MC.

Can we use your data for other studies?

After this study, your data may also be important for other scientific research in the field of middle ear complaints and/or for the further development of Aurisvue and OCT. For this purpose, your data will be stored in Erasmus MC for 15 years. In the consent form you indicate whether you agree with this. Do you not give permission? Then you can still participate in this survey. You get the same care.

What happens when unexpected discoveries occur?

During the investigation, we may happen to find something that is important for your health. The researcher will then contact your general practitioner or specialist. You will then discuss what needs to be done with your GP or specialist. With the form you give permission to inform your general practitioner or specialist.

Can you withdraw your consent to the use of your data?

You can withdraw your consent to the use of your data at any time. This applies to use in this study and to use in other studies. But beware: if you withdraw your consent, and have researchers already collected data for a study? Then they can still use this data.

Do you want to know more about your privacy?

- Do you want to know more about your rights regarding management of your personal data? Have a look at www.autoriteitpersoonsgegevens.nl.

Do you have questions about your rights? Or do you have a complaint about the processing of your personal data? Please contact the person responsible for the processing of your personal data. For your research that is:

  - Erasmus MC. See appendix A for contact data and website.
- If you have complaints about the processing of your personal data, we recommend that you first discuss them with the research team. You can also contact the Agent Dataprotection of the Erasmus MC in Rotterdam. Or you file a complaint at the Autority Personal data.

Where do you find more eer information about the study?

At the following website(s) you find more informatie about the study: www.toetsingonline.nl. After the study the website can give you a summary of the results of the study. You'll fin dit by searching for 'Feasibility of middle ear OCT imaging' (number: 80285)

11. Do you receive a compensation for participating in this study?

The additional measurements for the examination will not cost you anything. You will not receive any compensation if you participate in this study. You will, however, be reimbursed for the extra travel and parking costs incurred at Erasmus MC.

12. Are you insured during the study?

An insurance policy has been taken out for everyone who participates in this study. The insurance pays for damage caused by the investigation. But not for all damage. In Appendix B you will find more information about the insurance and the exceptions. It also states who you can report damage to.

13. Do you have questions?

Questions about the research can be put to the research team.
Do you have a complaint? Then discuss this with the researcher or the doctor who is treating you. Would you rather not? Then go to the complaints officer of the Erasmus MC or the Authority Personal data. In appendix A is stated where you can find these.

14. How do you authorize for participation with the study?

You can think about this research first. Then you tell the researcher whether you understand the information and whether or not you want to participate. Would you like to participate?

Then fill in the consent form that you will find with this information letter. You and the researcher will both receive a signed version of this consent form.

Thank you for your time.

15. Appendices tot his information

A. Contact data of the Erasmus MC
B. Information about insurance
C. Subject consent form

Bijlage A: contact data for Erasmus MC

Primary investigator
Dr. R.M. Metselaar
afdeling KNO-heelkunde, Erasmus MC
Dr. Molewaterplein 40
3015 GD Rotterdam, Nederland
Telephone: 010-7040120
Email: secr.knopoli@erasmusmc.nl

Complaints
If you have any complaints about the study, you can discuss them with the study doctor or your treating doctor. If you prefer not to do this, you can also contact the complaints officer of the Erasmus MC.

Complaints officer:
online form: https://forms.iprova.nl/8gzf62664c/415
Telephone: 010-704 4108
Erasmus MC, secretary of complaints
Antwoordnummer 55
3000 WB Rotterdam

More information about your rights regarding data management
For general information regarding your rights regarding the data management you can visit the website of the Autority of Personal data: http://www.autoriteitpersoonsgegevens.nl.

Het Erasmus MC heeft een Functionaris Gegevensbescherming (FG) aangesteld. De FG houdt toezicht op de naleving van de privacywetgeving en adviseert het Erasmus MC over de privacywetgeving (denk aan AVG). De FG is tevens de contactpersoon voor alle vragen die over privacy gaan, zowel voor u als betrokkene als voor de toezichthouder.
Email Functionaris Gegevensbescherming van het Erasmus MC:
functionaris.gegevensbescherming@erasmusmc.nl

Appendix B: information about insurance

Erasmus MC has taken out insurance for everyone who participates in the study. The insurance will pay for the damage that you have suffered as a result of taking part in the study. This concerns damage that you receive during the investigation, or within 4 years after the investigation. You must report damage to the insurer within 4 years.

Do you suffer from damage caused by the study? Claim it to this insurance company:

Name:	Centramed
Address:	Maria Montessorilaan 9, 2719DB Zoetermeer
Telephone:	070-3017070
E-mail:	info@centramed.nl
(Polisnummer:	624.100.042)

The insurance company pays a maximum of € 650.000 per person and € 5.000.000 for the complete study and € 7.500.000 per year for all studies by the same client.

Please note: the insurance does **not** cover the following damage:

- Damage due to a risk about which we have given you information in this letter. But this does not apply if the risk turned out to be greater than we previously thought. Or if the risk was very unlikely.
- Damage to your health that would also have occurred if you had not taken part in the study.
- Damage caused by you not or not properly following directions or instructions.
- Damage to the health of your children or grandchildren.
- Damage caused by a treatment method that already exists. Or through research into a treatment method that already exists

Deze bepalingen staan in het 'Besluit verplichte verzekering bij medisch-wetenschappelijk onderzoek met mensen 2015'. Dit besluit staat in de Wettenbank van de overheid (https://wetten.overheid.nl).

Appendix C: test subjects consent form

Belongs to: Feasibility of OCT for the middle ear

- I have read the information letter. I could also ask questions. My questions have been answered well enough. I had plenty of time to decide whether to participate.
- I know that taking part is voluntary. I also know that I can decide at any time not to participate in the study. Or to stop. I don't have to say why I want to stop.
- I give the researcher permission to provide my general practitioner or specialist with information about unexpected findings from the study that are important for my health.
- I give the researchers permission to collect and use my data. The researchers only do this to answer the research question of this study.
- I know that for the purpose of checking the survey, some people can see all my data. Those people are listed in this information letter. I give these people permission to view my data for this check.
- Would you like to tick yes or no in the table below?

I give permission to keep my data to use it for other research, as stated in the information letter.	Yes ☐	No☐
I give permission to ask me after this study to participate in future study.	Yes ☐	No☐

- I want to participate in this study.

My name is (participant): ……..
Sign: …… Date : __ / __ / __

I declare that I have fully informed this subject about the said study.

Will information become known during the study that could influence the subject's consent? Then I will let this test subject know in time.

Name investigator (or representative):…….
Sign:…… Date: __ / __ / __

The participant receives a complete information letter, together with a signed version of the consent form