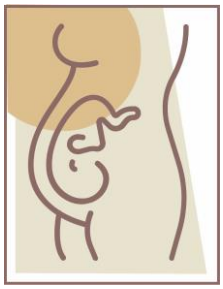
Subject information for participation in medical research



NIEM-O Study: A medical study on external monitoring of pregnant women during admission to the Obstetric High Care.

Official title: Non-Invasive monitoring at the obstetric high care

Introduction

Dear Madam,

With this letter, we would like to ask you to take part in a medical study. Participation is voluntary. You have received this letter because your doctor has admitted you to the Obstetric High Care (OHC) of Máxima MC (MMC). This information sheet contains information on the medical study, what it means for you, and what the pros and cons are from participating in the study. It is a lot of information. Please take the time to read the information and determine whether you wish to participate? If you wish to participate, please fill out the form in Appendix E.

Ask your questions

You can make your decision based on the information in this information sheet. We also suggest that you do this:

- Put your questions to the investigator who gave you this information.
- Talk to your partner, family or friends about this study.
- Read the information on www.rijksoverheid.nl/mensenonderzoek.
- Further information about participating in medical scientific research can be found in Appendix C - the enclosed brochure 'Medical scientific research'.

1. General information

MMC has set up this research project. Researchers, who can be doctors, midwifes, nurses and researchers, carry out the research in MMC at the ward. For this study, 47 subjects who are admitted to the OHC of MMC are required. The medical ethics review committee from Máxima Medical Center has approved this study.

2. What is the purpose of the study?

The aim of this study is to improve care at the OHC and to promote the health of you and your child. Monitoring your child and you during the pregnancy contributes to this. Our research focusses on the way pregnant women are currently monitored. We will hereby collect data about the registration of the uterine activity and the heart rate of you and your child during admission to the OHC, together with data about the outcome after delivery.

For example, information about the need for a caesarean section, the birth weight of your child and admission to the pediatric ward after delivery. We will also send you two surveys about your experiences with the monitoring method.

3. What is the background of the study?

You are pregnant and your doctor wants to admit you or has admitted you to the OHC. During your hospital stay, the mother's heart rate, the heart rate of the unborn child and the activity of the uterine muscle (contractions) are recorded to keep a close eye on the condition of you and your child. This is called a cardiotocogram (CTG).

The monitoring method (CTG)

Depending on your reason for admission, a CTG will be made one to three times a day. Uterine activity (contractions) is recorded by placing a button on your abdomen that is held in place by elastic banding around your waist. Your child's heart rate is measured by placing another button on your abdomen that is held in place by a second elastic band around your waist. See Figure 1 for this monitoring method. This way of registering has been used as standard care for decades.

Figure 1. CTG monitoring with elastic banding

Data collection is necessary to understand how CTG monitoring affects you and your child's outcomes. Outcomes that will be analyzed are for example how long you and your childs hospital stay is, how often caesarean sections are performed and the incidence of specific diseases. Additionally, we gather this information so that we can compare the findings with advancements in monitoring techniques. We want to collect data on a large scale. That is why we ask all women admitted to the OHC to participate in this study and for permission to use their data for scientific research.

4. What happens during the study?

How long will the study take?

Are you taking part in the study? This will take as long as your admittance to the OHC lasts. If you are readmitted, your data will also be collected.

Step 1: Are you eligible to take part?

First, we want to know if you are eligible to participate. You may participate in the study if you meet the following criteria:

- You are at least 18 years old
- You are admitted to the OHC

Unfortunately, you will not be allowed to participate in the study if you:

- Have a multiple pregnancy (twins/triplets)
- Have a pacemaker
- Have insufficient knowledge of Dutch or English language
- You or your unborn child have arrhythmia or cardiac disease
- Are admitted for a serious condition that happens when the body's immune system has an extreme response to an infection (sepsis)

Step 2: The monitor method

If you participate in this study, you will receive the same treatment and monitoring method as when you do not participate in the study.

Step 3: Study and measurements

No extra visits to the hospital are needed for this study. Measurements and data collection throughout the study are performed during your admission to the OHC. For an overview of the steps in this study, see Appendix B.

Monitoring method

You'll get the standard monitoring method. Two transducers are placed on the abdomen, which are held in place by two elastic bands. The CTG registration will be performed one to three times a day for at least 45 minutes, depending on the reason for admission. No registration will take place between these moments, unless there are other reasons making additional monitoring necessary.

Surveys about your experiences

We will ask you to complete two digital questionnaires. The questions are about your experiences with the monitoring method. We will send both questionnaires to your email address immediately after you have been admitted to the OHC and agreed to participate in the study. The first questionnaire is about your health while using the monitor method. You complete this questionnaire on the first day after admission. The second questionnaire is about your experiences with the device (the standard monitoring method). You complete this questionnaire on the day of your discharge from the hospital. It will take you approximately 3-5 minutes to complete the first questionnaire and approximately 5-10 minutes to complete the second questionnaire. Your experiences are of great importance for our research and will be included in the results of the research.

Apart from the questionnaires, you don't have to do anything extra for this study

5. What agreements do we make with you?

We want the study to go well. That is why we want to make the following agreements with you:

- You should contact your caregiver/the investigator in these situations:
  - You no longer want to take part in the study.
  - Your telephone number, address or email address changes.

6. What side effects, adverse effects or discomforts could you experience?

There are no side effects, adverse effects or discomforts related to participation in this study.

7. What are the pros and cons if you take part in the study?

Taking part in the study can have pros and cons. We will list them below. Think about this carefully and talk to other people about it.

Potential benefits of participating in the study may include:

- You can give your opinion about the current monitoring method, so we can improve this in the future.
- We hope to achieve better maternal and child outcomes in the future by gaining insight in the outcomes related to monitoring methods. You can play a part in this.

Possible disadvantages of participating in the study may include:

- The survey will take a maximum of twenty minutes of your time.

Don't want to participate?

You decide whether you want to participate in the study. Participation is voluntary. Not interested in participation? No explanation is necessary to explain why you don't wish to participate.

8. When does the study end?

The investigator will let you know if there is any new information about the study that is important to you. The investigator will then ask you if you want to continue to take part.

In these situations, the study will stop when:

- You have given birth (outcomes will be monitored until 6 weeks after giving birth)
- You do not have to be admitted anymore to the OHC at MMC
- You want to stop participating in the study yourself. You can stop at any time. Report this to your care provider immediately. You do not have to explain why you want to stop. You will then get the standard monitoring method.
- One of the following authorities decides that the study should stop:
    - MMC,
    - The government, or
    - The Medical Ethics Review Committee assessing the study

What happens if you stop participating in the study?

The investigators use the data that have been collected up to the moment that you decide to stop participating in the study. The investigation is complete when all measurements of all participants are collected.

9. What happens after the study has ended?

You will not be personally informed about the results of the study. After processing the data, the investigator will publish the results of the study in scientific journals.

10. What will be done with your data?

Are you taking part in the study? Then you also give your consent to collect, use, store and if necessary share your encrypted data with other researcher within this research field. These researchers are those who are likewise interested in the findings of this research and are located inside the MMC, in the area, in the nation, or overseas.

What data do we store?

Your personal data will be collected and stored for this research. Data such as your name, address, date of birth and data concerning your health and the delivery are collected. A number of data concerning your child are also collected and stored, such as gender, birthweight, Apgar scores, umbilical cord measurements, possible admission to the paediatric ward and general information about your child's health. The outcomes of your child's health will be collected until hospital discharge. When your child is discharged within the first four weeks after delivery, we will collect the data until four weeks after delivery.

Why do we collect, use, store and share your data?

We collect, use, store and share your data to answer the questions of this study. And to be able to publish the results. As a result, caregivers and researchers in the Netherlands and in the world have access to our knowledge and further research can possibly take place. Also performing the same research and thereby patient burden is prevented.

How do we protect your privacy?

To protect your privacy, we give a code to your data. We only put this code on your data. We keep the key to the code in a safe place in the hospital. When we process your data, we always use only that code. Even in reports and publications about the study, nobody will be able to see that it was about you.

Who can see your data?

In addition to the research team, some people can get access to your non-anonymised data at the research location. Including the data without a code. This is necessary to be able to check whether the study is being conducted in a good and reliable manner.
Persons who have access to your data for review are: a monitor working for Máxima MC Veldhoven, and national and supervisory authorities, for example, the Health and Youth Care Inspectorate. They will keep your data confidential. We ask you to give permission for this inspection.

For how long do we store your data and body material?

We store your data in the hospital for 15 years

May we use your data for other research?

After this study, your data may also be important for other scientific research in the field of monitoring pregnant women. For this purpose, your data will be stored in the hospital for 15 years. You give permission by signing the consent. Do you not give permission? You'll get the same care.

Share your data with other researchers
In order to make it possible to publish the results of this research in certain scientific journals and to give other researchers the opportunity to carry out further research, it is necessary to make anonymized data available. There will be no way to link data to you personally. You consent to the exchange of this data when signing the consent form.

What happens if there are accidental discoveries?
It is possible that during the study we discover something that is important for your health. In that case, the investigator will contact your caregiver. You will then discuss what needs to be done with your specialist. With the form, you give consent to inform your specialist.

Can you take back your consent for the use of your data?
You can take back your consent for the use of your data at any time. This applies both to the use in this study and to the use in other medical research. But please note: if you take back your consent, and the investigators have already collected data for research, they are still allowed to use this information

Do you want to know more about your privacy?

- Do you want to know more about your rights when processing personal data? Visit 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 who is responsible for processing your personal data. For the present, this is:
    - MMC. See Appendix A for contact details, and website.
- If you have any complaints about the processing of your personal data, we recommend that you first discuss them with the research team. You can also contact the Data Protection Officer of MMC. Or you can submit a complaint to the Dutch Data Protection Authority.

11. Will you receive compensation if you participate in the study?
Participation in this study will not cost you anything. Neither will you get any compensation if you take part in this study.

12. Are you insured during the study?
Insurance has been taken out for everyone who takes part in this study. The insurance pays for damage caused by the study. But not for all damage. You can find more information about this insurance and any exceptions in Appendix D. It also says who you can report damage to.

13. Exchange of information

The researcher will contact your main practitioner to request your medical information if your main practitioner does not work at MMC. This is required to gather all of your data, even if you were monitored at another hospital, are (temporarily) admitted to MMC, and will return to your original hospital. This includes, for example, the date of delivery, the start of your child and your health up to 4 weeks after your delivery. You consent to the exchange of this data.

14. Do you have any questions?

You can ask questions about the study to your caregiver or the research team. Would you like to get advice from someone who is independent from the study? Then contact Dr. L. Bok, paediatrician at MMC. He knows a lot about the study, but is not a part of this study. Do you have a complaint? Discuss it with the investigator or the doctor who is treating you. If you prefer not to do so, please visit the complaints officer of MMC. Appendix A tells you where to find this.

15. How do you give consent for the study?

You can first think carefully about this study. You have at least an hour to do this, and you can use more time if necessary. Then you tell the investigator if you understand the information and if you want to take part or not. If you want to participate, please fill out the consent form that is included. You and the investigator will both get a signed version of this consent form.

Thank you for your attention.

16. Appendices to this information

A. Contact details
B. Flow chart admission
C. Leaflet ‘Medical scientific research’
D. Information about the insurance
E. Consent form(s)

Appendix A: contact details for the MMC

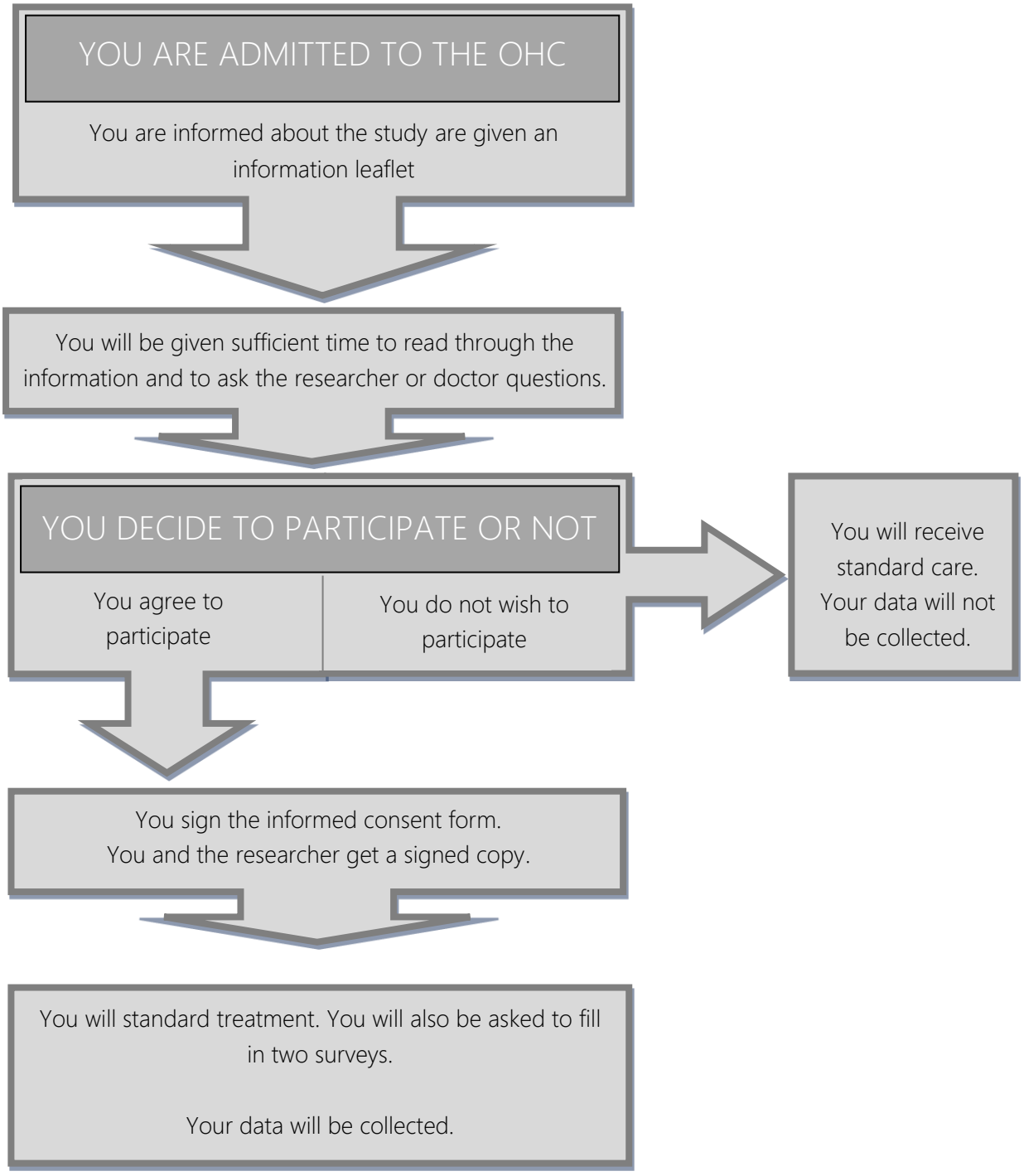
Investigators:
Drs. N.D. de Klerk, medical researcher gynaecology/obstetrics, Máxima MC Veldhoven
Ir. I. de Vries, researcher, Máxima MC Veldhoven
Dr. J. van Laar, gynaecologist-perinatologist, Máxima MC Veldhoven
Dr. M. van der Ven, technical physician, Máxima MC Veldhoven
Dr. A.F Fransen, gynaecologist, Máxima MC Veldhoven
Dr. H.J. Niemarkt, pediatrician, Máxima MC Veldhoven
Dr. Ir. R. Vullings, engineer
Prof. Dr. S.G. Oei, gynaecologist-perinatologist, Maxima MC Veldhoven
Telefoon: 040-8888384
Email: niemo.studie@mmc.nl

Independent expert:
Dr. L. Bok, pediatrician, Máxima Medical Center Veldhoven
Email: l.bok@mmc.nl
Phone (office): 040 8888270

Complaints:
If you have any complaints about the study you may contact the complaint mediator of Máxima MC Veldhoven.
Telephone: (040) 8889481
Email: klachtbemiddeling@mmc.nl
Department for quality and safety

Data Protection Officer:
If you have questions and/or comment regarding the processing of your personal data within Máxima MC, you can contact the data protection officer.
Telephone: (040) 8888366
Email: gegevensbescherming@mmc.nl
Website: https://www.mmc.nl/privacy

Appendix B Flowchart admission



Appendix C – Leaflet Medical Scientific Research

Appendix D: information about the insurance

The Máxima MC has taken out insurance for everyone who takes part in the study. The insurance pays for the damage you have suffered because you participated in the study. This concerns damage you suffer during the study or within 4 years after you participated in the study. You must report damage to the insurer within 4 years.

Have you suffered damage as a result of the study? Please report this to the researchers (contactdata can be found in *Appendix A)* and to this insurer:

The insurer of the study is:
Name insurer: Lloyd's Insurance Company S.A.
Address: Bastion Tower, Marsveldplein 5, 1050 Brussel, België
Policy number: MCIEEA23029

The insurance pays a maximum of €650.000 per person, a maximum of €5.000.000 for the entire study, and a maximum of €7.500.000 per year for all studies by the same sponsor.

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

- Damage due to a risk about which we have given you information in this sheet. 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 happened if you had not taken part in the study.
- Damage that happens because you did not follow directions or instructions or did not follow them properly.
- Damage caused by a treatment method that already exists. Or by research into a treatment method that already exists.

These provisions can be found in the 'Besluit verplichte verzekering bij medisch-wetenschappelijk onderzoek met mensen 2015' (Medical Research (Human Subjects) Compulsory Insurance Decree 2015'). This decision can be found in the Government Law Gazette (https://wetten.overheid.nl)

Appendix E: Informed consent form – subject

Belonging to the NIEMO-study: A medical study on external monitoring of pregnant women during admission to the Obstetric High Care.

- I have read the information sheet. I was able to ask questions. My questions have been answered well enough. I had enough time to decide if I wanted to take part.
- I know that taking part is voluntary. I also know that at any time I can decide not to take part in the study. Or to stop taking part. I do not have to explain why.
- I give the investigator consent to inform and contact specialist (s) who treats me that I am taking part in this study and to retrieve my and my child's data after birth, that are requisite for the research.
- I give consent to give my doctor or specialist information about accidental discoveries made during the study that are important for my health.
- I give consent to collect and use my data. The investigators only do this to answer the question of this study.
- I know that some people will be able to see all of my data to review the study. These people are mentioned in this information sheet. I give consent to let them see my data for this review.
- Please tick yes or no in the table below.

I give consent to share my coded data with other researchers.	Yes☐	No☐
I give consent to store my data to use for other research, as stated in the information sheet	Yes☐	No☐
I give consent to ask me after this study if I want to participate in a follow-up study.	Yes☐	No☐

- I want to take part in this study.

My name is (subject): ……..
Signature: …… Date : __/__/__

If there is another (authoritative) parent, legal representative(s) or guardian besides you (the mother), we also ask that person to give separate permission for the collection of your child's data after birth

Is there is another (authoritative) parent, legal representative(s) or guardian besides you?
☐ Yes
☐ No

If you answered YES, they must sign below for permission. If that person does not give permission, we are not allowed to collect your child's data.

The name of the other (authoritative) parent, legal representative(s) or guardian is:
……..

Signature: …… Date: __ / __ / __

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

If any information becomes known during the study that could influence the subject's consent, I will let this subject know in good time.

Investigator name (or their representative): .....
Signature:…… Date: __/__/__

The study subject will receive a complete information sheet, together with a signed version of the consent form.