

Subject information for participation in medical research

Data collection of monitoring of the condition of mother and child during delivery and the first six weeks after birth

Official title: Intrapartum monitoring: a prospective cohort

Dear Madam,

We would like to ask you to participate in a medical study. You have received this information letter because you will give birth and might be able to participate in this study. Participation is voluntary and requires your written consent.

Before you decide whether you want to participate in this study, you will be given an explanation on what the study is about. You can read about the medical study in this information sheet, what it means for you, and what the pros and cons are of participating in the study. It is a lot of information. Please take time to read the information and determine whether you wish to participate? If you wish to participate, please fill out the form in Appendix C.

Ask your questions

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

- Put your questions to the healthcare professional and/or researcher who gave you this information.
- Talk to your partner, family or friends about this study.
- Read the information on <https://www.government.nl/topics/medical-research>.

1. General information

This study is initiated by Máxima MC (MMC) Veldhoven and is executed by doctors, midwives, nurses, medical students and researchers. For this study, a total of 253 subjects are required. ZonMw and Máxima MC (location Veldhoven) are funding the research.

The Máxima MC Medical Research Ethics Committee (METC) have accessed and approved this study. The METC decided that our research falls under the Medical Research Involving Human Subjects Act (in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen), WMO). This means we are obligated to follow the rules laid out under this Act. General information about how a medical scientific study is monitored can also be found on the website of the national government: <https://www.government.nl/topics/medical-research>.

2. Background of the study

When you give birth at the hospital the heartrate of the mother, the heartrate of the unborn child and the contractions are continuously recorded. In this way we monitor the condition of you and your child. This recording is called a cardiotocogram (CTG). The heartrate of you and your child and the contractions are recorded by two buttons on your belly. These are kept in place by two elastic bands around your waist (figure 1). The signal quality of these recordings can be low due to your movements

or movements of the unborn child during delivery. Consequently, the buttons on your belly have to be repetitively repositioned during labour. To improve signal quality for measuring the heartrate of the unborn child, a small thread is attached to your child's head (scalp electrode) through the vagina after the membranes have ruptured (figure 2).



Figure 1. External conventional CTG monitoring with elastic bands.

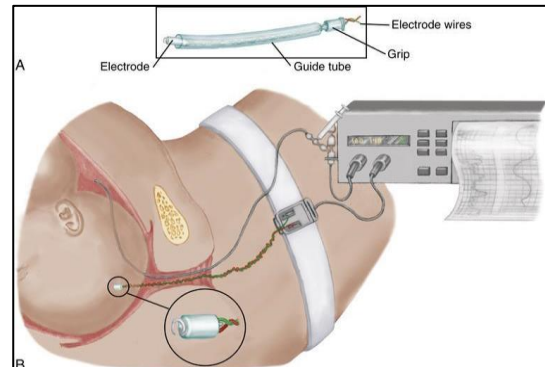


Figure 2. Internal measurement of the fetal heart rate of the unborn child by a scalp electrode.

3. Purpose of the study

This way of recording the CTG has been used as standard care for decades. Extensive research has been carried out on other methods of recording the condition of the mother and child during delivery. The goal is these research is to improve health conditions for both mother and child. We want to collect data of you and your child during labour where standard recording of the CTG was used. These data will be used to compare with a new monitoring device. We want to collect data from you and your child up to six weeks after delivery.

We want to collect data of 253 pregnant women and their child for this study. Therefore, we ask for you permission.

In addition, we ask all the women to complete two questionnaires after delivery (until a maximum of 48 hours). The questionnaires are about the childbirth experience and the experience with the CTG.

4. What participation involves

You are eligible for participation if you meet the following criteria:

- Minimal age of 18 years old
- You are 37 to 42 weeks pregnant
- You have an indication for fetal monitoring during labour
- Your unborn child is in a vertex position

You are not able to participate in this study if:

- You have insufficient knowledge of Dutch or English language
- You are pregnant with multiple babies (twins, triplets)
- Your unborn child has a cardiac arrhythmia (detected and confirmed during pregnancy by ultrasound)

- You have a cardiac arrhythmia
- You have a pacemaker
- It is already known that you will have a caesarean section or instrumental vaginal delivery, before participation in the study
- You participate in the study, but circumstances call for delivery of the baby by unplanned caesarean section before you are in active labour
- You are admitted to the hospital for serious condition that happens when the body's immune system has an extreme response to an infection (sepsis)

Differences with 'standard care'

After a maximum of 48 hours following birth, participants in this research will be asked to complete two online questionnaires. Your birth experience and your CTG experience are covered in these questionnaires. This is not part of routine medical care and should only take ten minutes. The questionnaires will be completed before you are going home. The data collection from you and your child will continue for up to six weeks after delivery. These data will be used for (future) scientific research. You do not have to do anything additional actions for this.

If you do not want to participate in the study

If you do not participate in this study, we will monitor the heartbeats and contractions in the same manner, the CTG monitoring. We will not use the data of you and your child for (future) scientific research.

5. Possible advantages and disadvantages

It is important that you carefully consider the possible benefits and disadvantages before you decide to participate in this study. You will receive standard care during delivery. If there is permission for the use of your data and data of your child, these data is always stored and used anonymously. Therefore participation in this study will not have adverse consequences for the care you receive. Participation in this study does not have any direct advantages for you. By participating you will help us to improve future care from women and their unborn child during the delivery.

6. If you do not want to participate or you want to stop participating in the study

It is up to you to decide whether or not to participate in the study. Participation is voluntary. If you do not want to participate, you will be treated and guided as usual during your delivery. You do not have to tell why you do not want to participate in this study.

If you do participate, you can withdraw from the investigation at any time, without giving any reason. However, we do ask you kindly to inform the researcher or healthcare professional. The data collected up to that point will be used for (future) research.

If there is any new information about the study that is important for you, the investigator will let you know. You will then be asked whether you still want to continue your participation.

7. End of the study

Your participation in the study stops when:

- All data collection has been completed (until six weeks after delivery).
- You choose to quit.
- The researcher/health care professional considers it best for you to quit.
- The gynaecologists of Máxima MC Veldhoven, the government or Medical Research Ethics Committee decides to stop the study.

The entire study ends when all measurements of the participants are collected. You will not be informed personally about the results of the study. After processing the data, the researcher will publish the results in scientific journals.

8. Usage and storage of your data

Your personal data and your child's data will be collected from the electronic patient file or questionnaires. Data such as your name, address, date of birth, data about you and your child during delivery, data about your health or the health of your child after delivery. The data collection from you will continue for up to six weeks after delivery. The collection, use and storage of these data is required to answer the questions asked in this study and to be able to publish the results.

Missing information of you and your child will be requested by your practitioner, primary care physician, obstetrician or gynecologist, the child health center or the pediatrician to receive this information. We ask your permission for the request of your data and the permission of the parent(s)/legal representative(s) for the request of child's data

Confidentiality of your data

In order to protect your privacy and the privacy of your child, data is encoded. Your name and other information that can directly identify you and your child will be omitted. Data can only be traced back to you and your child with the key of the code. The key of the code remains safely stored in the local research institute. The only persons who have access to the key to this code are the investigators listed in appendix A. There will be no way to link data of you and your child personally in reports and publications.

Access to your data for verification

Some people may have access to all of your data and your child's data at the local research institute, also to the data without code. This is necessary in order to check whether the study has been carried out properly and reliably. Persons who have access to your data for inspection are the committee that monitors the security of the investigation, an independent inspector hired by the investigator (for this study: Clinical Trial Center Maastricht) or national and international supervisory authorities, for example, the Health and Youth Care Inspectorate. They will keep your data confidential. We ask you and the legal representative(s) of the child to give permission for this inspection.

Retention period of your data

Your data must be kept for 15 years at the research location (MMC, Veldhoven). You consent to this.

Storage and use of data for other research

The data collected in this study may also be of importance for other scientific research in the field of fetal monitoring during delivery. Scientific information such as publications and anonymous data is available to everyone. To this end, 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

Data collected during this study will be analysed later, after the study has ended. Therefore unexpected findings in the data will no longer be relevant for your health and/or the health of your child at that time and will not be fed back for this reason.

Withdraw permission

You can withdraw your consent to the use of your personal data and the data of your child at any time. This applies to this research as well as to the storage and use for future research. The research data collected up to the moment you withdraw your consent will still be used in the study.

More information about your rights when processing data

For general information about your rights when processing your personal data, please consult the website of the Dutch Data Protection Authority. If you have any questions about your rights, please contact the Data Protection Officer of the MMC. See Appendix A for contact details and website.

If you have questions or complaints about the processing of your personal data, we advise you to first contact the coordination researcher. You can also contact the Data Protection Officer of the MMC. See appendix A for contact details, or the Dutch Data Protection Authority.

9. Insurance

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 B. It also says who you can report damage to.

10. No financial compensation for participation

Participating in this study, will not give additional costs for you. Because your participation in this study is entirely voluntary, you will not be given money or gifts to take part in this research.

11. Do you have any questions?

If you have any questions, please contact the coordinating investigator. For independent advice on participating in this research, you can contact the independent expert. He knows a lot about the study, but has no association with the study. All details can be found in Appendix A: Contact details.

If you have any complaints about the study, you can discuss this with the investigator or your threatening specialist. If you prefer not to, you can contact the complaints mediator of the MMC. All details can be found in Appendix A: Contact details.

12. Signing the consent form

When you have had sufficient time for reflection (at least 30 minutes during labour), you will be asked to decide on participation in this study. During delivery, you will have a maximum of 2 hours during labour to decide whether you want to participate in the study. If you want to participate, we kindly ask you to confirm this by signing the consent form, attached in appendix C. If you sign this form, you indicate that you have understood the information about participation in the study and agree the terms. Both you and the investigator will receive a signed copy of the consent form.

Thank you for your attention.

13. Appendices

- A. Contact details
- B. Information about the insurance
- C. Informed Consent Form

Appendix A: Contact details

Investigators:

Dr. J.O.E.H. van Laar, gynaecologist-perinatologist, Máxima MC Veldhoven

Dr.ir. M.B. van der Hout-van der Jagt, Technical University of Eindhoven, Máxima MC Veldhoven

Drs. A. van Barschot, researcher, department of gynaecology and obstetrics, Máxima MC Veldhoven

Telephone: 040-888 83 84

Email: NIEMIstudie@mmc.nl

Independent expert:

Dr. K.P. Dijkman, pediatrician, Máxima MC Veldhoven

Telephone: 040-888 93 50

Email: k.dijkman@mmc.nl

Complaints:

If you have any complaints about the study, please contact the complaints mediator.

Telephone: 040-888 94 81

Email: klachtbemiddeling@mmc.nl

Department for quality and safety

Officer data protection:

If you have any questions and/or comments with regard to the processing of your personal details within MMC, you can contact the officer data protection.

Telephone: 040-888 83 66

Email: gegevensbescherming@mmc.nl

Website: <https://www.mmc.nl/privacy>

Appendix B: 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 researcher and the 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: MCIEEA23030

The claims representative of the study is:

Name: Ralph van Helden

Address: Beursplein 37, 3001 DD Rotterdam

E-mail: ralph.vanhelder@lloyds.com

Telephone number: + 31(0)102052110

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 C: Subject Consent Form [Patient]

Data collection of monitoring of the condition of mother and child during delivery and the first six weeks after delivery

Official title: Intrapartum monitoring: a prospective cohort

The information regarding the child is valid for the parent(s)/legal representative(s) of the child.

- I have read the information letter. I was also able to ask questions. My questions have been sufficiently answered. I have had enough time to decide if I want to join this study.
- I know participation is voluntary. I also know that I can decide at any time not to participate or to stop participating without giving a reason.
- I give permission for researchers to collect and use my personal and medical data and the data of my child from the electronic patient file or questionnaires for the purpose of answering the research question in this study.
- I give permission for researchers to request medical information from me and/or my child after delivery from my practitioner, primary care physician, obstetrician, gynaecologist, child health center or pediatrician to answer the research question of this study.
- I know that in order to monitor the study, some people may have access to all my data. These people are listed in this information letter. I consent to such access by these people.
- I give permission to keep my data stored for 15 years at the research location.
- Please fill in everything in the grey boxes:

Authority child:

- ☐ Both parents / legal representatives declare to sign the consent form.
- ☐ Parent 1 / legal representative 1 declares sole parental authority over the child.

Subject / parent 1 / legal representative 1:

- I want to participate in this study.
- I consent to the collection and use of my child's data for the study as described in the information letter.

Name subject (initials, first and last name): _____

Date of birth: ____/____/____

Signature: _____ Date: ____/____/____

Additional consent subject / parent 1 / legal representative 1:

I give consent to contact me again after this study for a follow-up study.	☐ Yes	☐ No
I give consent for the collection and use of my data and data of my child for comparable studies in the future and to share data anonymously with other researchers.	☐ Yes	☐ No

Parent 2 / legal representative 2 (if applicable):

- I give consent to the collection and use of my child's data for the study as described in the information letter.

Name parent 2 / legal representative 2: _____

Signature: _____ **Date:** ____ / ____ / ____

Additional consent parent 2 / legal representative 2:

I give consent for the collection and use of my child's data for comparable studies in the future and to share data anonymously with other researchers.	☐ Yes	☐ No
---	------------------------------	-----------------------------

----- **Fill in below by the researcher (or her representative)** -----

- I hereby declare that I have fully informed the participant about this study.
- If information comes to light during the course of the study that could affect the study subject's consent, I will inform her of this in a timely fashion.

Name of investigator (or her representative): _____

Signature: _____ **Date:** ____ / ____ / ____

* *The study subject will receive the full information sheet together with a signed copy of the consent form.*

Appendix C: Subject Consent Form [Researcher]

Data collection of monitoring of the condition of mother and child during delivery and the first six weeks after delivery

Official title: Intrapartum monitoring: a prospective cohort

The information regarding the child is valid for the parent(s)/legal representative(s) of the child.

- I have read the information letter. I was also able to ask questions. My questions have been sufficiently answered. I have had enough time to decide if I want to join this study.
- I know participation is voluntary. I also know that I can decide at any time not to participate or to stop participating without giving a reason.
- I give permission for researchers to collect and use my personal and medical data and the data of my child from the electronic patient file or questionnaires for the purpose of answering the research question in this study.
- I give permission for researchers to request medical information from me and/or my child after delivery from my practitioner, primary care physician, obstetrician, gynaecologist, child health center or pediatrician to answer the research question of this study.
- I know that in order to monitor the study, some people may have access to all my data. These people are listed in this information letter. I consent to such access by these people.
- I give permission to keep my data stored for 15 years at the research location.
- Please fill in everything in the grey boxes.

Authority child:

- ☐ Both parents / legal representatives declare to sign the consent form.
- ☐ Parent 1 / legal representative 1 declares sole parental authority over the child.

Subject / parent 1 / legal representative 1:

- I want to participate in this study.
- I consent to the collection and use of my child's data for the study as described in the information letter.

Name subject (initials, first and last name): _____

Date of birth: ____ / ____ / ____

Signature: _____ Date: ____ / ____ / ____

Additional consent subject / parent 1 / legal representative 1:

I give consent to contact me again after this study for a follow-up study.	☐ Yes	☐ No
I give consent for the collection and use of my data and data of my child for comparable studies in the future and to share data anonymously with other researchers.	☐ Yes	☐ No

Parent 2 / legal representative 2 (if applicable):

- I give consent to the collection and use of my child's data for the study as described in the information letter.

Name parent 2 / legal representative 2: _____

Signature: _____ **Date:** ____ / ____ / ____

Additional consent parent 2 / legal representative 2:

I give consent for the collection and use of my child's data for comparable studies in the future and to share data anonymously with other researchers.	☐ Yes	☐ No
---	------------------------------	-----------------------------

----- **Fill in below by the researcher (or her representative)** -----

- I hereby declare that I have fully informed the participant about this study.
- If information comes to light during the course of the study that could affect the study subject's consent, I will inform her of this in a timely fashion.

Name of investigator (or her representative): _____

Signature: _____ **Date:** ____ / ____ / ____

* *The study subject will receive the full information sheet together with a signed copy of the consent form.*