Information sheet for participation pregnant woman in NOGBS study

GBS carriage in pregnant women and protection of their baby

Dear Madam,

You have received this letter because we would like to ask you to take part in this medical-scientific study. All pregnant women who are planning to give birth in this hospital are eligible to participate in this study. Participation is voluntary and requires your written consent. The study takes place in the hospital of admission.
Before you decide whether you wish to participate in this study, you will be given an explanation about what the study involves. Please read this information carefully. If you have any questions please ask the investigator for further explanation. You can find the contact details in the appendix to this letter (Appendix A).
The Medical Research Ethics Committee (METC) AMC has approved this study. General information about the assessment of research can be found in the general brochure on medical research.

1. Purpose and aim of the study

One in five woman is carries the group B streptococcal (GBS) bacteria in the intestine or vagina. In most cases this does not cause any problems for the mother or the child. However, a small minority of the babies will become severely ill due to this bacteria in the first days to weeks after birth. It is not clear why some babies develop severe disease and others do not. Antibodies from the mother can protect the baby against GBS disease. The mother can make these antibodies during pregnancy, and transfer them to the blood of the baby before birth by the placenta. However, it is not known how much of these protective antibodies are necessary to fully protect the baby.
The Academic Medical Center (AMC) of Amsterdam investigates severe bacterial infections. In this study we look at the level of antibodies that is needed in the blood of mothers and babies to protect against GBS the child against GBS disease. In the future, this could lead to a vaccination for pregnant women to protect their children from developing GBS disease.

2. What participation involves

Participating in this medical-scientific study will not change the medical treatment for your delivery.
If you choose to participate, the following may be extra:

- **Blood collection**
  We will collect 1-2 tubes of blood to measure the amount of antibodies against the GBS bacteria.
  After the baby is born, the placenta will be born. In the placenta there is still some blood of the baby left behind. For this study we will collect a tube of blood from the placenta. If there is left-over material of blood of the umbilical cord available from routine care, we will also use this for the study. Your child will not be punctured for this study.

We ask for separate permission to contact you to ask for permission to collect material that is left over from the dried blood spots (heel prick test) of your child, that is routinely collected by the GGD/RIVM.

- **GBS carriage: genital swab**
  We collect a genital swab (from vagina and anus). The physician or nurse will collect the swab. It is not painful.
- **Medical data**
  We also ask your permission to collect the medical information about your pregnancy, delivery and the health of your baby in the first three months after birth from your gynecologist/ midwife, general practitioner and possibly pediatrician.

- Please contact us (Appendix A) if your child is hospitalized in the first three months after birth.

3. Possible advantages and disadvantages

It is important that you weigh the possible benefits and disadvantages before you decide to participate. Participation involves minimal disadvantages. Drawing blood from the mother may be painful or cause some bruising. The self-collection of a genital swab is not difficult or painful, but some woman can experience some discomfort.
Due to participation in this study it is possible that we find out that you are carrier of the GBS bacteria, which we did not have found in routine clinical practice. The result of the test will have no effect on this current pregnancy. In case of any future pregnancy your gynecologist or midwife will decide with you if you want to have antibiotic treatment during labor in order to reduce the chance of infecting your child. This is standard clinical practice for GBS carriage in the Netherlands.
Your participation will help to make better GBS prevention possible.

4. If you do not wish to participate or you wish to stop participating in the study

It is up to you to decide whether you participate in this study or not. Participation is voluntary. If you do participate in the study, you may always change your mind and decide to stop, at any time during the study. You do not have to say why you do not wish to participate or are stopping.
The data and material collected up till that time will be destroyed.

5. End of the study

Participation stops when your child is discharged from the hospital or you choose to stop. We ask for separate permission to contact you in the future to ask for permission to retain residual blood from the dried blood spots (heel puncture) of your child.

6. Use of data and bodily material

For this study it is necessary to collect and use your bodily material and medical data.

Privacy

To protect your privacy each study subject receives a code. Name and other personal data that could directly identify a person will then be deleted. Only with the key to this code can you be traced. The key to this code will be safely stored at the local research institute. Some people may access your

medical and personal data at the research institute, even the data without a code. This is to check whether the study has been conducted in a proper and reliable manner. People who may access the data are representatives of the AMC as initiator of the study and the Healthcare Inspectorate. They will keep the data secret. We ask your consent for this access. The investigator will store the data for 15 years.

Findings of importance

It cannot be ruled out that, during future scientific research with you blood or bodily material, findings of importance for your health, or the health of your children/family members will be discovered. If this indicates a serious health problem or health risk for which treatment is available, we will notify you. We will always consider carefully if it is necessary to inform you of such findings. In the context of this decision we will also ask advice from the hospital committee.

7. Storage data and bodily material in the MeninGene Biobank

The collected data and/or blood samples/tissue samples may be important for additional and future research to severe bacterial infectious diseases. Therefore we will store your data and bodily material for 50 years in the MeninGene Biobank. If you sign the Biobank consent form (C2) you give permission for this storage. Participation is voluntary. You do not have to say why you do not wish to participate. The AMC has drafted a Biobank Code “Reglement MeninGene”. This contains the rules for the confidential handling of data and the material and the purposes for which this may be used. You can ask the researchers for this Code. The Biobank Audit Committee supervises the Biobank.

Sharing data and bodily material in future studies with different research groups

By collaboration with other research teams and sharing data, we can answer new research questions. We would like to ask your consent to share data and bodily material with other research groups for future research into bacterial meningitis.

We also ask for permision to share your body material with commercial companies or institutions from abroad, for example manufacturers of vaccines. For sharing data with commercial companies we will ask permission from the Biobank Audit Committee. For sharing data with institutions from outside the EU it is possible that there may be other rules for personal data protection. We will share the data only via the code, never using the personal information (name, date of birth etc). If you do not wish us to share material for future research, you can state this separately on the consent form.

Withdrawal of consent

You can always decide to stop, at any time during the study, by filling in the “withdrawal form” (Appendix B). After withdrawal all data and material will be destroyed. If the samples have already been analysed, the results will still be used

8. Study subject insurance

This study is not associated with any risks for you. The METC AMC has therefore declared that there is no need to take out additional insurance.

9. Informing treating specialist

Your treating specialist (gynaecologist/midwife) is always aware of your participation in the study.

10. Costs or compensation

The study is free of charge. You will not receive payment for participation.

11. Any questions?

If you have any questions, please contact the study team. If you would like independent advice about participation in this study, you may contact Doctor B. Jaeger (Paediatric Neurology AMC). She knows about but is not involved in this study.
If you have any complaints, you may contact the complaints' officer at your hospital. All the relevant details can be found in **Appendix A**: Contact details.

12. Signing the consent forms

Your written permission indicates that you have understood the information and consent to the participation in this study. The signature sheet is kept by the investigator. You will receive a copy or a duplicate copy of this consent form.

Thank you for your attention.

12. Appendices to this document

A. Contact details
B. Withdrawal form "MeninGene Biobank"
C. Informed consent forms
   - C1: Informed consent for **study participation**
   - C2: Informed consent for **storage data/material Biobank**
D. Medical Scientific Research Brochure. General Information for Study Subjects (version 01-03-2017)

Appendix A: Contact details investigators

Contact details Tergooi

Dr. E. van Asbeck, gynaecologist
Tergooi ziekenhuizen
Gynaecologie
Tel: 088 – 753 1 753
E-mail: evanasbeck@tergooi.nl

Contact details AMC

M.N. van Kassel, MD, PhD student
Academic Medical Center
Neurology H2-224
Tel: 020 - 566 1564
E-mail: m.n.vankassel@amc.uva.nl

Dr. M.W. Bijlsma, Pediatrician
Academic Medical Center
Neurology H2-217
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Tel: 020 - 5663942
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Independent expert

B. Jaeger, Pediatric Neurology
Academic Medical Center
Pediatric Neurology, H7-270
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Tel: 020 - 5663942
E-mail: b.jaeger@amc.uva.nl

Complaints' officer

Klachtenfunctionaris
Postbus 10016
1201 DA Hilversum
T: 088 753 14 10
E-mail: klacht@tergooi.nl

FOR PARTICIPANT

To withdrawal consent in the future

Appendix B2: Mother - Withdrawal of Consent Form for Biobank MeninGene

- I hereby withdraw my consent for participation in the MeninGene Biobank
- I understand that if my bodily material has already been analysed and used in research, this cannot be withdrawn or destroyed
- I understand that if my medical data has already been analysed and used in research, this cannot be withdrawn or destroyed
- I hereby request the administrator of the MeninGene Biobank to destroy the collected and stored data and bodily material of me.

Name Mother: Date of Birth: __ / __ / __

Signature: Date:__ / __ / __

Appendix C1: Consent Form for participation mother in NOGBS study

- I have read the subject information form. I was also able to ask questions. My questions have been answered to my satisfaction. I had enough time to decide whether to participate.
- I want to participate in this study.
- I know that participation is voluntary. I know that I may decide at any time not to participate after all or to withdraw from the study. I do not need to give a reason for this.
- I give permission for my treating specialist to be informed about my participation in this study and to request results of previous collected cultures.
- I give permission for information to be requested from my GP/treating specialist(s)/midwife about my previous and current pregnancy and its outcome.
- I give permission to obtain residual blood material of my pregnancy for the purpose stated in the information sheet.
- I give permission that my treating specialist will be informed if the collected genital swab is tested positive for GBS.
- I know that some people can access my data. These people are listed in this information sheet.
- I consent to my data/blood samples/bodily material being used in the way and for the purpose stated in the information sheet.
- I consent to my data being stored at the research location for another 15 years after this study.
- I consent to contact me in the future to ask for permission to retain residual blood from the dried blood spots (heel puncture) of my child.

  □ yes

  □ no

Name participant:
Date of birth: __ / __ / __
Signature: **Date:** __ / __ / __

I hereby declare that I have fully informed this study subject 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 him/her of this in a timely fashion.

Name of investigator (or his/her representative):
Signature: **Date:**__ / __ / __

C2: Consent Form for storage data and bodily material in Biobank

- I have read the subject information form. I was also able to ask questions. My questions have been answered to my satisfaction. I had enough time to decide whether to participate.
- I know that participation is voluntary. I know that I may decide at any time not to participate after all or to withdraw from the study. I do not need to give a reason for this.
- I know that some people can access my data. These people are listed in this information sheet.
- I consent to my data and bodily material being stored in encoded form without stating my name or other personal data that could directly identify me in the MeninGene Biobank.
- I consent to my encoded research data being stored for another 50 years after this study. It may be used for research in the future into severe infectious diseases.
- I know that there is a possibility that during future scientific research findings of importance, indicating a serious health problem or health risk for which treatment is available, could be discovered. If so, I or the my treating specialist will be informed.
- I give permission to share my collected data and bodily material with other research groups.
  - □ yes
  - □ no
- I give permission for research with the data and material by institutions from abroad .
  - □ yes
  - □ no
- I give permission for research with my data and material by commercial companies.
  - □ yes
  - □ no

Name mother:
Date of birth: __ / __ / __
Signature: **Date: __ / __ / __**

I hereby declare that I have fully informed this study subject 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 him/her of this in a timely fashion.

Name of investigator (or his/her representative):
Signature: **Date:__ / __ / __**