

Information letter for representative



Dear Sir, Madam,

We would like to draw your attention for the following: your partner or relative has been admitted to the hospital because he or she has been diagnosed with meningitis, an infection of the membranes covering the brain. The meningitis is caused by a bacterium and also referred to as bacterial meningitis. Since many years, we from the department of neurology of Academic Medical Center in Amsterdam (AMC) conduct scientific research on bacterial meningitis. For this research we collect clinical data from patients who have been admitted with bacterial meningitis. By collection data on bacterial meningitis we hope to get more insight in the disease and identify new treatments.

At this moment we investigate whether there is a genetically increased susceptibility to bacterial meningitis and we attempt to collect DNA from as many bacterial meningitis patients as possible. For this study, which is carried out in all Dutch hospitals, we need cooperation of as many patients as possible. Therefore, we want to ask your partner or relative to participate in this study. When you decide to let your partner or relative participate in the study, the research can be done in the hospital where he or she is admitted.

Before you decide to let your partner or relative to take part in the study, it is important to know more about the research. Read this information letter carefully and discuss it with people in your environment. You can read the brochure 'medical research' of the Dutch Ministry of Health, Welfare and Sports as well. In this brochure you can find a lot of general information about medical research. If you have further questions after reading this letter and the brochure, these can be answered by the researchers. At the bottom of this letter you can find the contact addresses of the researchers and the independent physician, who is not involved but has a lot of knowledge about the research project.

Background and objectives

Besides the clinical data we are very interested in DNA, the building blocks of the human cells, of patients with bacterial meningitis. Everyone's DNA is unique and different. Small variations in DNA may contribute to increased risk of infections. Recent studies show there is increasing evidence for this concept. Bacteria causing meningitis reside in the nose and throat of many healthy people. It remains unclear why these bacteria cause meningitis in some patients and cause no problem at all in others.

Study-design

Data collection

For the research we use clinical data of your partner or relative collected on admission in the hospital, such as symptoms of the disease, results of blood laboratory tests and radiological examinations (CT or MRI scans). These investigations are part of the standard care and not performed additionally on account of the research.

Blood sampling

Two additional samples of 7 ml blood are collected from your partner or relative, if possible combined with a regular blood withdrawal for diagnostic purposes. From these blood samples DNA will be isolated in the AMC after which it will be analyzed for specific DNA variation which may be more frequent in patients with bacterial meningitis.

Leftover cerebrospinal fluid after diagnostic puncture

We can use leftover cerebrospinal fluid of your partner or relative derived from the lumbar puncture performed on admission. This cerebrospinal fluid will be used to investigate proteins and other factors involved in bacterial meningitis.

European meningitis database (MeninGene Biobank)

We ask your permission to add the clinical data, blood and cerebrospinal fluid of your partner or relative in a European database, called the MeninGene Biobank. Data in this database will be stored in an encrypted fashion guaranteeing the privacy of your partner or relative. The European database will be made available to European bacterial meningitis researchers and has the objective to find new treatments. By combining large groups of patients the chance of finding new clues for therapeutic options increases.

Storage of DNA and cerebrospinal fluid

The DNA and leftover cerebrospinal fluid of your partner or relative may be important for future research on bacterial meningitis. Therefore, we want to store, after completion of this research, the remaining DNA and cerebrospinal fluid for 50 years. It will be stored in the AMC and is only accessible for researchers in the AMC or researchers associated with the European database. The researchers will be unable to identify you as all clinical data, blood and cerebrospinal fluid samples are stored in a coded fashion, without reference to the name, date of birth or patient identification number of your partner or relative.

Results of future research

In specific cases, results of the DNA or cerebrospinal fluid may be of direct importance for the health of your partner or relative. When this occurs we would like to inform him or her. Sometimes it takes years before further research is performed and if this occurs we will approach him or her by mail with the question if he or she still wants to be informed about new findings that potentially influence your health. Following this letter he or she can decide if he or she wants have more information on the specific findings. Subsequently, you he or she can decide if he or she wants to get treatment for the identified health threat or partake in preventive measures. If you do not want to have the DNA or cerebrospinal fluid of your partner or relative stored in the biobank for future research you can state this on the informed consent form.

Contact in case of further studies on bacterial meningitis

Finally, we ask your permission to approach your partner or relative for future research about bacterial meningitis. Before he or she takes part in any new study, he or she will receive information about the specific study and we will ask again for informed consent.

What is expected of you, additional burden

If your partner or relative participates in this study:

1. Two additional blood samples of 7 ml will be collected, if possible at a regular blood withdrawal.
2. Your permission is asked to store the data and DNA of your partner or relative in a coded fashion in a European database.
3. Your permission is asked to approach your partner or relative in the future for further meningitis research.

Benefits and risks of the study

Your partner or relative does not have direct benefit from this study. Therapies or preventive strategies identified as a result of this study may be beneficial to future meningitis patients.

A disadvantage can be an additional blood withdrawal if the blood samples can not be collected during a regular blood withdrawal. The risks of a venous blood withdrawal are minor.

Voluntary participation

You decide if you want to give permission to let your partner or relative participate in this study. Participation is completely voluntary and you can withdraw your consent at any moment without providing a ground for withdrawal. In that case the data will be removed from the database and the DNA and cerebrospinal fluid samples of your partner or relative will be destroyed. More information can be read in the brochure 'medical research' of the Dutch Ministry of Health, Welfare and Sports. If

you don't want your partner or relative to participate in the study it has no implications for further treatment of your partner or relative.

After this research

For your partner or relative the study is completed after the blood withdrawal. The results of this study may give rise to future studies, for which we may approach your partner or relative if you granted us permission to approach him or her for future research.

Confidentiality

We are very careful with the data. Personal data are coded with a unique number. The key to this code only is known in the AMC; the coordinating researchers and research team will have entry to this code. This code will also be used to store DNA, leftover cerebrospinal fluid, radiological images and discharge letters. In case of publication, personal data will be kept confidential.

The health-inspection (inspectie voor gezondheidszorg – IGZ), the medical ethical committee of the AMC, and auditors can obtain access to source documents to check the data. Research data will be stored for 15 years. After this period data will be destroyed.

Insurance

The medical ethical committee of the AMC has exempted the study from insurance obligations for participants, because no additional risks attributable to participation to this study are present.

Questions

If you have further questions about the study, you can ask the neurologists that coordinate the study in the AMC, dr. M.C. Brouwer or prof. dr. D. van de Beek. You can consult an independent physician as well, dr. R.M.A. de Bie. This physician is not directly involved in the study, but has substantial knowledge about it.

We appreciate your taking the time to read this information letter.

Sincerely,
the MeninGene-team

Contact MeninGene-team:

Researchers

Prof. Dr. D. van de Beek, neuroloog
Dr. M.C. Brouwer, neuroloog

Academisch Medisch Centrum
Neurologie H2-217
Postbus 22660, 1100 DD Amsterdam
Tel: 020-5663674/5666079/5663682
E-mail: meningitis@amc.nl

Contact independent physician:

Dr. R.M.A. de Bie, neuroloog
Academisch Medisch Centrum
Postbus 22660, 1100 DD Amsterdam
Tel: 020-5663842 (choice 3)

Informed consent form MeninGene study – representative

CRF number: _____



MeninGene

My permission is asked to give informed consent for participation in the MeninGene study for:

Name:

Date of birth:

- I declare that I have read the information letter of the abovementioned study (version 1) and that I understand the information. I had sufficient time to consider participation in the study and I had the opportunity to ask questions concerning the study. These questions have been answered to my satisfaction.
- I give permission for participation in the abovementioned study.
- I give permission that two 7 ml tubes of blood are drawn from the person I represent for isolation and analysis of DNA.
- I give permission to include the medical data of the person I represent, in a way that is not retraceable to him or her, (pseudonymised) in a European database.
- I am aware that participation in this scientific study is strictly voluntarily, and I am aware that consent for participation can be withdrawn at any moment without provision of ground, also after given written informed consent.
- I give permission to the members of the medical ethical board, the inspection of health care and representatives of the sponsor of the study to look through the medical data of the person I represent and research data.
- I give permission to process the research data for purposes as described in the information letter.
- I give permission to store the research data of the person I represent for 15 years.
- I give permission that the DNA and liquor of the person I represent is stored for 50 years.
- I do/ do not* give permission that the person I represent can be contacted in the future for other scientific studies on bacterial meningitis or follow-up. (*cross out what does not apply to you)
- I do/ do not* want to be informed about potential findings that are relevant for the state of health of the person I represent (or the state of health of the family of the person I represent). (*cross out what does not apply to you)

Name (representative):

Relation to patient:

Address (patient):

Telephone number (representative):

Date:

Telephone number (patient):

Signature:

The investigator declares to have informed the representative of the patient completely and correct.

Name local investigator:

Date:

Signature:

Two original copies of the informed consent form need to be signed, one for the representative and one for the investigator.