

## Information letter for the partner



Dear Sir, Madam,

We would like to draw your attention for the following: your partner, relative or close friend 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. To investigate if the environment plays part in acquiring meningitis, we want to collect DNA of the partner and close friends of the patient as well. We can use that as a control group. Therefore, we want to ask you to participate in this study. When you decide to participate in the study, the research can be done in the hospital where your partner, relative or close friend is admitted.

Before you decide to take part in the study, it is important to know more about the research. Read this information letter carefully and discuss it with your partner, friends or family. 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**

#### *Blood sampling*

Two additional samples of 7 ml blood are collected. 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.

#### *European meningitis database (MeninGene Biobank)*

We ask your permission to add your blood in a European database, called the MeninGene Biobank. Data in this database will be stored in an encrypted fashion guaranteeing your privacy. 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*

Your DNA may be important for future research on bacterial meningitis. Therefore, we want to store, after completion of this research, the remaining DNA 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 your blood samples are stored in a coded fashion, without reference to your name or date of birth.

### *Results of future research*

In specific cases, results of the DNA or cerebrospinal fluid may be of direct importance for your health. When this occurs we would like to inform you. Sometimes it takes years before further research is performed and if this occurs we will approach you by mail with the question if you still want to be informed about new findings that potentially influence your health. Following this letter you can decide if you want have more information on the specific findings. Subsequently, you can decide if you want to get treatment for the identified health threat or partake in preventive measures. If you do not want to have your DNA or cerebrospinal fluid 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 you for future research about bacterial meningitis. Before you take part in any new study, you will receive information about the specific study and we will ask again for your informed consent.

### **What is expected of you, additional burden**

If you participate in this study:

1. Two blood samples of 7 ml will be collected.
2. Your permission is asked to store your data and DNA in a coded fashion in a European database.
3. Your permission is asked to approach you in the future for further meningitis research.

### **Benefits and risks of the study**

You do 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: 2 blood samples will be collected. The risks of a venous blood withdrawal are minor.

### **Voluntary participation**

You decide yourself if you want to participate in this study. Your participation is completely voluntary and you can withdraw your consent at any moment without providing a ground for withdrawal. In that case your data will be removed from the database and your DNA samples will be destroyed. More information can be read in the brochure 'medical research' of the Dutch Ministry of Health, Welfare and Sports. If you do not want to participate in the study it has no implications for your further treatment.

### **After this research**

For you personally the study will be completed after the blood withdrawal. The results of this study may give rise to future studies, for which we may approach you if you granted us permission to approach you for future research.

### **Confidentiality**

We are very careful with your 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.

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**

Patient information MeninGene (partner) – Version 1 30-06-2014

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 and we hope that you are willing to participate in this study.

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)

CRF number: \_\_\_\_\_

- 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 the 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 for isolation and analysis of DNA.
- I give permission to include my medical data, in a way that is not retraceable to me, (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 my medical data and research data.
- I give permission to process the research data for purposes as described in the information letter.
- I give permission to store my research data for 15 years.
- I give permission that my DNA is stored for 50 years.
- I do/do not\* give permission for being 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 my state of health (or the state of health of my family). (\*cross out what does not apply to you)

Name (participant):

Telephone number (participant):

Address (participant):

Date:

Signature:

The investigator declares to have informed the participant completely and correct.

Name local investigator:

Date:

Signature:

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