Westfälische Wilhelms-Universität Münster

UKM Universitätsklinikum Münster

Klinik für Kinder- und Jugendmedizin
– Allgemeine Pädiatrie –

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_____
Surname , First name

_____
date of birth

"Characterization of diseases of the ciliated epithelium including primary ciliary dyskinesia (PCD)"

Your information sheet

Dear Patient,

We would like to ask you if you are willing to participate in a research study. On the following pages you can find information about the study. Participation in the study is voluntary. If you choose to participate in the study, you can withdraw at any time and for any reason. Your decision to not participate in the study has no impact on the treatment of your disease.

Please take your time to read the following pages carefully. If you have further questions, please ask your doctor.

Background

You have been diagnosed with the disease primary ciliary dyskinesia (PCD). The surface of the airways (respiratory epithelium) is equipped with movable, hair-like structures (cilia) that transport particles (e.g., dust, pollen, bacteria) out of the airways by a percussive movement. When the cilia do not beat properly, the cleaning of the respiratory tract is disturbed, so that there may be recurrent infections. PCD is a genetic congenital disease. Each gene comes as a duplicate in our body´s cells. In most cases, PCD is diagnosed when a faulty copy of the gene is inherited from both parents. If you

have one defective copy of the gene and one healthy copy of the gene, you do not have PCD.

Aim of the study

The aim of this study is to find the exact cause (the responsible gene) for the occurrence of PCD and to learn how this error affects the function of the cilia. The findings are intended to better understand the progression of the disease and to develop new treatment options in the long term.

Your contribution to the study

To determine if you have PCD, we have already done a swab from your nose with a small brush. We would ask you if we may store this brushing sample as well as data obtained from this brushing sample. The sample from your nose is examined for research purposes in a research laboratory, and then it is stored for further investigation. In addition, we would like to ask you for permission to use your blood or isolated DNA for genetic studies. It will require only one time a 5 - 10 ml blood sample. This means that you and your parents, and perhaps also your brother or sister, would require a single blood sample donation.

The only material that is used in the course of this investigation (blood, cells from the nose, tissue, sperms) was already obtained during the diagnostic procedure and the material would otherwise be discarded.

Benefits and Risks

You will probably have no direct benefit from the study. However, the research may help to better understand the disease so that new treatments can be developed.

Information and Privacy

The legal basis for processing the aforementioned personal data is the consent in accordance with Article 6 (1), subsection a EU-DSGVO. Your consent to participate in this study also means that information about your health condition and other information are taken from your medical record. All data is stored as a pseudonym (i.e., your name and date of birth are replaced by a code number) and all material is identified by the

code number. The transfer of data is done only by using the number code. Only researchers, staff and inspectors will have access to this information in the study.

Questions

If you have questions about this study, please turn to your attending physician or the Director of Studies.

I have received a copy of the patient information.

Patient: Surname, First name	signature