Register and Biobanks for autoinflammatory diseases (AID)

Information letter for adults

Ladies and Gentlemen,

we contact you, because you suffer from a disease with recurrent fever episodes.

These are the most known autoinflammatory diseases = AID:
Familial Mediterranean Fever (FMF), tumor necroes factor-receptor-1-associated periodic syndrome (TRAPS), and chronic infantile neurological, cutaneous, and articular (CINCA)-syndrome or systemic juvenile idiopathic arthritis (SJIA) also called Still’s disease, periodic fever, aphthous stomatitis, pharyngitis, adenitis syndrome (PFAPA) and further new AID, which are only defined by their symptoms, as well as the nonbacterial osteomyelitis (NBO).

We would like to collect your disease data from ambulant treatment, hospitalization or from laboratory examinations in one register and archive samples of yours for further examinations in a biobank. This does not affect your treatment, which you continue to discuss and decide with your physician.

Contact:
The register is organized by PD Dr. med. E. Lainka, Dr. med. U. Neudorf (University hospital Essen, Pädiatriche Rheumatologie, Hufelandstr. 55, 45122 Essen, Tel: 0201/723-4141) and the Senior Consultant of the Children’s clinic Krefeld (Prof. Dr. med. T. Niehues, HELIOS Klinikum Krefeld, Lutherplatz 40, 47805 Krefeld, Tel: 02151/322301). They are your contacts regarding the topic data administration.

Responsible for the sample collection (Biobank) are Prof. Dr. med. D. Föll (Director of the department for pediatric rheumatology and immunology at the university hospital Münster (Office: Frau C. Marinca, Tel: 0251/8358178, Fax: 0251/8358104, email: cornelia.marinca@ukmuenster.de) and PD Dr. med. H. Wittkowski (Clinic for pediatric rheumatology and immunology at the university hospital Münster).
What do we do?
The disease data of patients suffering from autoinflammatory diseases throughout Germany will be documented online in the AID register at the diagnosis and during the course of disease by your attending physician. Monitoring facilitate the determination of successes and failures and to draw conclusions out of it for the treatment. Additionally your physician will send you a link to your email at each follow-up, so that we will know directly from you, how you are feeling. The family anamnesis is very important, because the concerned diseases may partially be transmitted to the next generation. For that we have a genealogical tree (parents, siblings and patient) in the diagnosis form, in which positive molecular genetic findings and sick relatives may be introduced without personal-related details.

Biobank
In the scope of your regular treatment laboratory tests are carried out. Apart from the documentation of the standard laboratory examinations serum shall be taken for the examination of biomarker (biological agents in the blood of a patient, which point to normal or pathological processes in the body) and a sample for determination of DNA (= information carrier of the hereditary material) for the examination of genes possibly associated with autoinflammatory diseases. The biomarker will be taken as often as possible during your follow-ups (each time ca. 2 ml, that is ½ teaspoon). To be able to control additional blood components, the blood samples will be stored in the biobank Münster for 10 years and then destroyed. The samples will also be destroyed, if you withdraw your consent to the register.

The scientific examinations of the laboratory samples will be carried out at the clinic for pediatric rheumatology and immunology at the Universitätsklinikum Münster, but may also be transmitted to other cooperating scientific institutions for specific questions. This is made without personal-related details. The leftovers of the samples will be destroyed in the third-party laboratory or returned to the biobank.

As soon as the management of the clinical trial in cooperation with the participating centres realizes that certain issues for the improvement of therapy have to be scientifically solved, a research project is initiated. If the samples in the scope of this project shall be otherwise used and analysed, an ethics committee shall be consulted.

Who and what is documented?
German pediatric clinics, many specialised ambulances and laboratories participate in this research project. If you would like to know, which disease data will be introduced into the register, you may have a look at or download the four questionnaires (master data, diagnosis, follow-up, therapy) and the patient’s questionnaire on the homepage of the AID register (https://prst.gpoh.de/aid/formulare.asp).
Data protection
No data, which permit an allocation to a certain person, will be transmitted. To register the patients your physician will give you a code number using a random generator (PID). All samples and data from your medical record will be equipped with this PID and only your physician is able to allocate the PID to a person. Data will be stored in safe place under the PID number and protected from external access. The patient’s questionnaire also will be linked with the register using the PID. Pseudonymised data will be evaluated for research purposes. Results will be exclusively displayed in summary statistics, which do not permit any conclusions to certain individuals. Each physician of a centre only has access to the data introduced by himself. The management of the clinical trial have access to the data of all centres. All information will be kept strictly confidential.

A transfer of anonymised partial data regarding the disease history to a cooperating centre (see homepage) by the management of the clinical trial of the AID register will only be realized on request with an explicit question.

Because the data sets are not always complete, we as clinical trial management (s. a) kindly request you to consent us asking questions to your physician, to complete missing information.

There is always the risk of confidentiality in case of any collection, storage, and transfer of data from your biomaterial in the scope of a research project (e.g. the possibility to identify you), in particular as regards the information of your hereditary material. These risks cannot be completely excluded and will even rise the more data are linked, particularly if you (e.g. for genealogy) publish genetic information in the internet.

National cooperation and financing
We have a cooperation with the Deutschen Rheumaforschungszentrum (DRFZ) (German rheumatism research centre), which collects data about „basic set of information in the infancy“ for AID (1x/year). In order to prevent your physician from double documentation (introduction in the AID register and in the basic information set) or from causing confusion, we kindly request you to consent, that the basic set data of the online register may be transferred to the DRFZ with their own ID-number. The questionnaires regarding HRF and SJIA may be seen on the homepage of the AID register. The AID register is currently supported by the BMBF (Federal Ministry for Education and Research) and the GKJR (Association for children’s and juvenile rheumatology).

International cooperation: We cooperate with the „Eurofever Register“ of the European Organization PRINTO (Paediatric Rheumatology InterNational Trials Organisation), which also has an online database, in which patient’s data suffering from AID are collected. For details please access http://www.printo.it/eurofever. After your consent we will transmit basic data to increase the number of patients and the quality of our work by international cooperation. The circumstances in which this is realized are described in the chapter data protection.
Further a project-related data exchange with JIR-Cohort (Juvenile Inflammatory Rheumatism-Cohort) is done. In this cohort a common AID module was created for the AID register and the AID biobank, which may be used project-related from both sides. All register will not permit anybody to allocate those data to any person. The link of data and person will only be possible for your physician.

This is dependent on your written agreement
We are hereby asking you to participate in the AID register, to consent to further laboratory examinations and to storage of samples in the biobanks. The samples will be stored for scientific purposes. The participation is voluntarily and may be withdrawn at any time without giving reasons and without any disadvantages for your medical care. In case of withdrawal the data that has already been collected will be deleted and all blood samples destroyed.

Contact
If you have further questions, do not hesitate to contact us directly. For further information access http://www.AID-register.de. You may keep this information text with your personal belongings.

We thank you in advance for your cooperation and confidence and remain with best regards

PD Dr. med. E. Lainka Prof. Dr. D. Föll
- Clinical trial manager AID register - - Clinical trial manager biobank-