Krebsprädispositionssyndrom-Register 01

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Information for adult patients

Cancer-Predisposition-Syndrome-Registry-01

- Self-registration -

Dear Patient,
your physician has informed you that you have been diagnosed with a cancer predisposition syndrome. One main feature of this genetic condition is an increased cancer risk.
The medical care for individuals with cancer predisposition syndromes has not been standardized in the past. For specific cancer predisposition syndromes, participation in surveillance programs may be useful to detect and treat cancer(s) at an early stage.

Our registry has been established in order to pursue the following aims:

- To assemble a database with medical and genetic information from a large group of individuals with cancer predisposition syndromes. By doing so, we learn the natural history of cancer predisposition syndromes. The resulting knowledge will be used for recommendations for patients and health care professionals.
- To offer advice to your physician regarding the evaluation and interpretation of important findings related to your health. Due to the fact that we receive, evaluate and interpret a large number of such findings, we hope that our analysis may improve the quality of your medical care.
- To collect for research purposes blood samples and (if applicable) bone marrow and tumor specimens from patients with a cancer predisposition syndrome. Our research aims to better understand the genetic basis of cancer predisposition syndromes. For example, not all cancer predisposition syndrome causing genes are known. In addition, many of the genetic factors that negatively or positively influence the clinical course of patients with a cancer predisposition syndrome remain unidentified. Therefore, we aim at uncovering these modifying factors. Finally, by genetically analyzing tumor specimens from individuals with a cancer predisposition syndrome, we endeavor to discover the tumor-specific molecular mechanisms leading to cancer.

Brief Overview

Current state of knowledge: More than 50 cancer predisposition syndromes have been described. For many of these conditions, the precise cancer risks are unknown. For several cancer predisposing conditions, cancer surveillance strategies are recommended; however, little is known about the effectiveness of these recommendations. In addition, the genetic basis of cancer predisposition as well as the molecular mechanisms in cancer cells in patients with these conditions are poorly understood.

Study design: Our registry represents a natural history study. We collect medical information, radiological images and findings, genetic testing results, biospecimen such as blood and if available, bone marrow and tumor specimens from individuals with a cancer predisposition syndrome, in order to learn more about cancer predisposition syndromes and their associated cancers.

Procedures and processes: You contact the registry team on yourself to arrange the registration in the CPS-R01 registry. The education about the project is provided by telephone or in a personal conversation with a registry doctor. Copies of your medical findings/physician's letters and radiological images, which were collected in the course of standard examinations, as well as your genetic findings will be sent by yourself by postal service, fax or as an encrypted e-mail to the registry. Another possibility is to give the registry team the permission to obtain the above-mentioned information from the attending physicians. Since this is a long-term investigation that addresses the course of a condition over several years, the study has no defined duration. Therefore, results from follow-up investigations will be forwarded by yourself to the registry or will be collected from the attending physicians by the registry team with your permission. Because the registry collects information from multiple individuals with cancer predisposition syndromes, these measures result in knowledge related to the long-term course of different cancer predisposition syndromes.

If you would like to support biological research, we will be able to provide and sent tubes for blood samples. At the time that blood draws are normally completed for your medical care, additional blood samples can be taken and sent to the registry. If, for example, an operation is planned due to a tumor, you can contact the registry team in advance, which will then organise the shipment of a sample that is not otherwise required for your treatment.

The Risks and Benefits of Participation

Expected individual benefit:
Donating your biospecimen and medical data will not necessarily lead to a direct benefit to you. Our analysis serves primarily as scientific research and is not intended as actionable conclusions for your health. Nevertheless, the research may lead to findings that may be of importance to your health. In the situation, when an analysis reveals evidence of a severe previously unknown condition, that can potentially be treated or prevented, we may want to contact you in order to give you this information (see below).

In case you do not wish to receive this type of feedback, please check the box containing “no” on the informed consent. Any time, you can change your decision for or against this feedback option by letting us know. However, please note that you may be obligated to disclose health related information that you

receive through our registry, if you prefer this option, to other parties such as health- or life insurance companies. This may be a disadvantage for you.

The statement above is also relevant to genetic analyses and the discovery of genetic conditions. Therefore, this information may be relevant for your family members and family planning.

In the long-term, biospecimen and data collected through our registry is meant eventually to improve the care of patients with cancer predisposition syndromes (possibly including participants of the registry). For example, we would like to explore the role of regular evidence-based surveillance strategies. In addition, we offer your treatment team the opportunity to assess important findings. Because of receiving and evaluating a lot of these examinations, we have a comparatively large amount of experience with the disease. Therefore, we expect a high quality of our assessment and, if necessary, a benefit for your care.

General Benefit of the Registry:
Medical studies of this kind aim at a better understanding of the processes associated with disease development and improvement in diagnosis and care. Other patients with a cancer predisposition syndrome not participating in this research may benefit from our findings because our research aims at improving the care of all affected patients. Through the collection of biospecimen from individuals with a cancer predisposition syndrome, cancer research in general is advanced. There may be benefit for patients with cancer even in the absence of a cancer predisposition syndrome. We know that mechanism playing a role in individuals with a cancer predisposition syndrome may be relevant for cancer patients on the whole. In theory, it is possible that our research contributes to better therapy and prognosis of cancer patients.

Risks and Disadvantages of participation:
Blood draws are normally performed throughout your medical care. On these occasions, we would like to collect an extra 5-10 ml (one to two teaspoons) of blood for our biobank. This extra blood does not lead to extra risk for you. Since our study is a natural history study, there are no additional physical risks.

A tumor specimen is collected for research purposes only when a biopsy or tumor resection is performed as part of the patient's medical care. The size of the collected tumor specimen cannot be predicted as it depends on the size of the removed tumor sample. It is assured that research samples will be collected only if there is sufficient tumor material for diagnostic and therapeutic decisions for the patient. Therefore, the collection of tumor specimen for our registry does not impose additional risks.

Every ascertainment, storage, transfer of data is associated with the risk of breaching the confidentiality of the data (e.g. risk of identifying your person/information), which may be especially relevant for genetic information. It is impossible to entirely exclude this type of risk. This risk increases with the amount of connected data, especially if you are publishing genetic information in the internet on your own. Please see below regarding data and material security.

Purpose of collecting biospecimen:
Collected blood and tissue samples will be stored. We plan research on the mechanisms of cancer development utilizing these materials. We may use your biospecimen to produce long-living cell culture, to investigate the behavior of cells including when exposed to specific drugs. The samples are reserved for research related to the underlying condition. For example, we would like to determine why certain individuals with a cancer predisposition have a higher cancer rate than others with the same condition.

Also, we would like to elucidate molecular mechanisms of cancer development occurring in cancer cells. We also plan genetic studies that may involve studies of the entire genetic material (e.g., genome). The biomaterial and data will be available for research purposes for an unlimited period of time.

Protection of your biospecimen and data:
Biospecimen will be stored in the biobank of Hannover Medical School of indefinite duration. Clinical data will be stored on the secured XClinical (biomedical software company) server in MARVIN, the main data management system of the German Society of Pediatric Oncology and Hematology. All identifying information (name, date of birth, address, etc.) will be replaced by a code for research purposes. Only after this process, biospecimen and data will be made available for research. Transfer of identifying information to researchers or others such as insurances und employers does not occur.

Only coded biospecimen and data are used for research conducted by universities, research institutes or companies. It is possible that our registry data will be connected to your data in other databases, in accordance with the law and appropriate ethic committee approvals. For example, if you have a tumor for which you are receiving treatment on a clinical trial, information entered for this trail may be coupled our database and vice versa. Authorization to use biospecimen and data in a research study is limited to a specific researcher and project. The researcher is prohibited from using or passing on the biospecimen and data for additional purposes without permission. Remaining material is returned to the Hannover Medical School biobank or is destroyed.

Prior to using the biospecimen and data for a research project, a researcher must obtain an institutional ethics board approval. Institutional ethics board approval ensures that appropriate steps are taken to protect the rights and welfare of subjects of a research study. Publications are written in an anonymized fashion to prohibit identification of individual participants. This implies the situation, if data is entered into scientific online databases. A publication of your entire genetic information (genome) is impossible without your explicit written permission.

In order to consult with your physician regarding your medical care, our registry keeps a locked file with identifying information (e.g. name, date of birth, address). Dissemination of identifying information to researchers or other parties (e.g., insurances, employers) does not occur. **If you live in Germany, identifying information may be exchanged with the study group that is in charge of your cancer treatment plan as well as the German Childhood Cancer Registry in Mainz**.

Financial benefits to you or the biobank:
You will not be paid for allowing us to collect and store your biospecimen and data. You will not receive financial or other compensation, should findings resulting from the research on your biospecimen become commercially valuable. Your biospecimen stored in the biobank of Hannover Medical School is the property of the CPS-R01 of the German Society of Pediatric Oncology and Hematology. You authorize the registry to use your data for research purposes. Your specimen and data will not be sold. However, the biobank can ask researchers for an expense allowance for providing specimen to collaborating researchers.

Other Questions and Concerns

Is it possible that you will be contacted regarding the registry?
You regularly pass on medical results of check-ups to the registry team or (if you have given your consent) the registry team regularly obtains medical results of check-ups from your treating physicians. In case of missing data, it could be useful that you are contacted at a later time point in order to request additional information or specimen. Also, this contact could occur to request your permission for connecting your data with other databases or in order to give feedback to you or your physician on findings that may be relevant to your health. The contact is established according to your information in the informed consent, exclusively via you directly or via your supervising medical team.

In case you do not wish to be contacted, please check the box containing “no” on the informed consent.

What is your right of withdrawal from the registry?
Any time and without justification and disadvantages you may withdraw your consent that allows us to use your biospecimen and data. In case you withdraw your consent, you may decide whether your specimen should be destroyed or be anonymized. In the latter situation, we delete the identification code that allows us to connect a specimen to you. One has to keep in mind that such an anomymization process cannot entirely exclude the small chance that a specimen can be tracked back to you. Deletion of data may be limited technically feasibility, however.

You can also decide whether your already collected data should be deleted or may be further used in anonymised form. Data can only be deleted under the conditions of Art. 17 DSGVO.

As soon as the purchase of the biomaterials and other data relating to your person has been deleted (anonymisation), destruction is no longer possible. In addition, data from analyses already carried out can no longer be removed.

In case you would like to withdraw your consent, please contact:

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Is your participation voluntary?
Your participation in this registry is voluntary. In case you prefer not to participate, you will experience no disadvantage.

Where can I get additional information?
Should you have additional questions, please contact your physician prior to giving your consent. You can also contact Prof. Kratz or Prof. Pfister. Information regarding findings can be found on www.krebs-praedisposition.de.

We are happy to address your questions.

Sincerely

Christian Kratz, MD Stefan Pfister, MD