Storage and further use of biological material and of data for biomedical research

Information pamphlet for patients

Dear Patient

You have been asked to participate in the Swiss Kidney Stone Cohort. We ask you to give us your consent that the samples and data taken from you may be stored in the above-mentioned biobank (Biobank of the Swiss Kidney Stone Cohort) and may be further used for biomedical research. Your consent is voluntary.

The most important information is summarized for you below, so that you can make that decision, and of course we will inform you about your rights.

If you have questions or want to know something in addition, please contact your doctor, who will provide you with further information.

General information and objective of the Biobank

Kidney stones occur worldwide in all populations with relatively high incidence. There are different types of kidney stones and also the size strongly varies. Nevertheless, the exact formation in most cases is until today still unknown. To be able to understand better the formation of kidney stones, as well as the possible risk and/or triggering factors for kidney stones, and to be able to derive measures for the prevention of kidney stones, a national kidney stone patient cohort is now set up for the first time in Switzerland. That means, blood and urine samples are collected throughout Switzerland from patients with kidney stones and are stored in a so-called Biobank. These blood and urine samples are then used for future research projects for the better understanding of kidney stones.

Confidentiality of the data

All data will be anonymized. Before transferring your samples and data to researchers within and outside the hospital, they are anonymized such that researchers do not know from whom the samples were taken.

Only under certain requirements, which must be authorized by the appropriate ethics committee, those in charge of the Biobank (but not external researchers) can find out your identity again, for example if additional samples or data are needed.

This is called reversible (undoable) anonymization (also called pseudonymization), which means that information that could identify you (like name, date of birth, place of residence, patient's number etc.) is changed with the help of a code, so that for the researcher no conclusion on you as a patient is possible anymore (for example, by assigning a number to the person). Nevertheless, the coding key is stored by the Biobank so that you can be identified again under certain conditions, which must be authorized by the relevant ethics committee, for

example if additional samples or data are needed. During the trial, the ethics committee can view the original data. During the whole trial and with the above-mentioned controls, the confidentiality of your information is strictly protected. Your name will not arise in any way in reports or publications released about the trial.

Voluntary nature of the participation

Your participation in this Biobank is voluntary. If you renounce participation, you have to expect no disadvantages for your further medical care. The same is valid if you revoke your consent at a later time. **You can revoke your consent at any time without explanation**. In the event of revocation, your samples and data collected up to the time point of the revocation will be kept in encoded form and further used for scientific projects or destroyed according to what you specify in your consent. Without revocation your consent is also valid after death.

What does your consent mean?

If you agree, your samples and data may be kept in a Biobank for research purposes. Thus they are made accessible to biomedical research. Researchers can use these samples and data for biomedical research projects, which must be granted in advance by the responsible research ethics committee – where required by law.

Your consent is also valid for projects in the future. Hence, you will not be informed if your samples and data are used. Your consent will also not be asked again – except where the law or the responsible ethics committee requires the consent to be renewed.

Costs and compensation

Additional costs in connection with your participation will originate neither to you nor to your health insurance companies. Should additional costs originate from your participation that do not result within the scope of the regularly carried out treatment, these costs are covered by Swiss Kidney Stone Cohort. You receive no compensation for participation.

Benefits for the participants

Thanks to your participation, the findings can possibly be of benefit to future patients with the same disease.

Risks and inconveniences

No risks are to be expected for you, since future examinations are carried out on the stored and deep-frozen blood and urine samples and not directly on you.

Incidental findings

For incidental findings that may help you in the prevention, detection and treatment of existing or future expected disease, you have the choice: a) you would like to be informed about these findings directly, b) you would not like to be informed, or c) you leave the decision to the treating physician (see Declaration of consent).

Process of your participation

If you decide to participate in the Swiss Kidney Stone Cohort you will have the same examinations as if you do not participate. These examinations include blood samples, urine samples and completing questionnaires about nutrition.

In addition, you are asked to complete a questionnaire on physical activity and to supply a blood sample for a DNA (genetic information) analysis.
With your participation in the Swiss Kidney Stone Cohort your data and samples can be used for biomedical research purposes. Thus the results from the blood and urine samples are recorded in the Biobank, the blood and urine samples are stored and possibly used for a research project at a later time point.

The following table gives you an overview of the planned consultations.

Regardless of whether you choose to participate in the Swiss Kidney Stone Cohort or not, you are asked to attend the following dates.
The nutrition diary, the blood and urine samples, and the discussion of results will, however, also be carried out without participation in the Swiss Kidney Stone Cohort.

	Today	**In approx. 2 weeks**	**In approx. 4 weeks**	**In approx. 3 months**	**Annual examination (3 years)**	**Phone call (every 2 years)**
Information to patients orally and delivery of written patient information	√					
*Declaration of informed consent **		√				
Nutrition diary		√		√	√	
*Nutritional assessment (interview, ~1h)**		√		√	√	
*Questionnaire on nutrition**		√		√	√	
*Questionnaire on physical activity **		√		√	√	
Blood and urine samples are collected		√		√	√	
*DNA Analysis **		√				
Discussion of results and beginning of treatment if indicated			√			
*Interview on general health**						√

Additional examinations / evaluations because of participation in the Kidney Stone Biobank are identified with an asterisk and in italics.

Obligations of the study participant in the Swiss Kidney Stone Cohort:

As a study participant you are obliged:

- to follow the medical instructions of your investigator and adhere to the trial plan
- to inform your investigator about the course of the illness and report new symptoms, new complaints and changes in the condition (if necessary: also after the trial end / termination until the adverse effect wears off)
- to inform your investigator about the concomitant treatment with another doctor, and about the intake of medication. The medications also include all self-bought and/or alternative medicine preparations available without medical prescription.

Contact person

In case of uncertainties that arise during or after the completion of study-participation you can turn any time to the following contact persons:

- Clinical investigator:
- Address:
- Telephone number:

By surrendering your samples to the Biobank, you make a valuable contribution to biomedical research. We thank you warmly for your support.

If you have questions, please contact:

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