Neuropathological changes in the Wall of the large Bowel of Patients with functional Bwel Disorders

PATIENT INFORMATION AND INFORMED CONSENT FORM

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Head of the clinical study: PD Dr. Claudia Rudroff

Patient information about the clinical study

On neuropathological changes of the intestinal wall in patients with bowel evacuation disorders.

Dear Patient, [1]

we would like to recruit you to participate in our clinical observational study investigating defecation disorders. For this purpose, we need samples of intestinal tissue and blood from you as well as some medical data.

In the following text, we explain the objectives and the process of the clinical study. As required by law, this study was positively evaluated by an ethics committee. The study is initiated and organized by the Evangelisches Klinikum Köln Weyertal gGmbH, Clinic for General and Visceral Surgery, Department of Visceral Surgery and functional surgery of the lower gastrointestinal tract, Weyertal 76, 50931 Cologne.

In the subsequent informative discussion with one of our physicians, you will have the opportunity to address any points that are unclear to you. Of course, you will be given sufficient time to think about whether to participate.

Your participation is voluntary. You will only be included in this clinical trial if you give your written consent. If you do not want to participate or withdraw from it later, this will not have any disadvantages for you.

1. Why is this study being conducted?

We are conducting the study to investigate possible medical correlations of the defecation disorder - from which you also suffer. This may be a bowel transport disorder in the sense of chronic constipation or a defecation disorder with difficulties in effortless and/or complete bowel emptying.

With a comparative study of larger groups of individuals, we aim to identify biomedical correlates to improve our understanding, detection, and treatment of this disease.

[1] In the context of this text, the masculine designation always includes the feminine designation.

2. What biomaterials and data are involved?

We require so-called biomaterials for this purpose. These are samples of intestinal tissue taken from you during your hospital stay for the purpose of diagnosing and treating your defecation disorder. For the clinical study, we only use samples that are no longer needed and would otherwise be destroyed. In addition, we will draw 15 ml of blood from you, the serum (liquid portion of the blood) of which will be used for additional testing.

The data collected from you mainly comprises medical information about you. For this purpose, we conduct a detailed medical history interview with you. Personal data such as date of birth and name are not significant for us in this context and are "pseudonymized" (see below).

3. How will the biomaterials and data be used?

The biomaterials and data you provide will be used exclusively for research into defecation disorders. However, the exact scientific questions cannot be named in an all-encompassing manner at this time. It is possible that genetic tests will be performed on your biomaterials, which will include an examination of your genetic material (genome) if we find evidence of an origin.

The biomaterials and data are to be stored for an indefinite period of time and made available for medical research on this clinical picture. You have the right to specify individual limitations for this in your declaration of consent (e.g. the exclusion of certain research, the exclusion of the transfer of the materials to third parties). You can also determine whether you want to limit the use of your data and biomaterials over time.

With the transfer of the biomaterials to the Clinic for General and Visceral Surgery, Ev. Klinikum Köln Weyertal, they become the property of the clinic. Furthermore, you authorize the clinic to use your data.

4. What personal benefit do you get from participating in the study?

For your personal health, you have no direct advantage or benefit from the donation of your biomaterials and data. Their evaluation is solely for research purposes and not to draw conclusions about your health.

However, it is possible in individual cases that an evaluation result is of considerable importance for your health. This is particularly the case if there is an urgent suspicion of a serious, previously undetected disease that could be treated or its outbreak prevented. In such a case, feedback may be provided to you if you specifically request it. In doing so, please note that you may be required to disclose the health information you obtain through such feedback to other parties (e.g., prior to taking out a health or life insurance policy) and could suffer disadvantages as a result.

Since examinations of your genetic material are also possible, the above text may also refer to your genetic predisposition to certain diseases. Information about your genetic makeup could also have significance for your family members and family planning.

You can change your decision for or against a feedback option at any time by notifying us (see below).

6. What risks are associated with study participation for you?

a. Health risks
The tissue samples are taken during the bowel surgery that is medically necessary as part of your treatment and are normally destroyed afterwards. This tissue donation collection is therefore not associated with any additional health risk for you.

In addition, we will draw 15 ml of your blood (the equivalent of about four tablespoons), which is associated with the minor risks for you of a normal blood sample. For example, pain or a bruise (blue spot) may occur at the puncture site. In extremely rare cases, a blood clot (thrombosis), localized inflammation at the puncture site or permanent damage to blood vessels or nerves may occur.

In principle, you are insured for damages caused by the study-related blood collection (according to §2 para. 1 No.13 b SGB VII). This also includes accidents that occur on the direct way to and from the study center (EVK Köln Weyertal) for sample collection. Claims are to be submitted to the Unfallkasse NRW, Postfach 330420, 40437 Düsseldorf.

b. Other risks

There are confidentiality risks (e.g. the possibility of identifying you) whenever data from your biomaterials are collected, stored and transmitted as part of research projects. These risks cannot be completely excluded. In the following point we explain how we protect your data and biomaterials.

7. Who has access to your data or biomaterials and how are they protected?

a. All data directly identifying your person (name, date of birth, address, etc.) will be replaced by an identification code (pseudonymized) after preservation of the biomaterials for the clinical study. Afterwards, the data set is recoded and stored. This double coding excludes an identification of your person by unauthorized persons to the greatest possible extent according to the current state of knowledge. Only in this form are the biomaterials and data made available to research.

b. The data directly identifying you will remain at the facility where the samples and data were obtained and will be stored there separately from the biomaterials and medical data. The samples and data can therefore not be assigned to your person without the involvement of this facility. Such assignment will only occur in order to supplement additional data from your medical records or to contact you again if you have consented to being contacted. Data identifying you will not be shared with researchers or other unauthorized third parties, such as insurance companies or employers.

c. The coded biomaterials and medical data can be passed on to universities, research institutes and research companies, possibly also abroad, for more precisely defined medical research purposes according to previously defined criteria. In doing so, the data may also be linked to medical data in other databases, provided that the legal requirements for this are met. Biomaterials and data released to researchers may only be used for the predetermined research purpose and may not be passed on by the recipient for other purposes. Unused material will be returned to the institution or destroyed.

d. Scientific publications of results are exclusively anonymized, i.e. in a form that does not allow any conclusions to be drawn about your person. Publication of the entirety of your genetic information (whole genome) is excluded.

8. Do you have a financial benefit from the use of your biomaterials and data?

You will not receive any remuneration or compensation for the use of your biomaterials and data. If a commercial benefit is achieved from the research, you will not be involved in this.

9. Whom do I contact if I have further questions?

Consultations at the testing station

You will have the opportunity for further counseling sessions with the study director named on page 1 or another investigator. In these, you can clarify further questions in connection with the clinical study. We will also be happy to answer questions concerning your rights and obligations as a patient and participant in the clinical trial.

If you wish to withdraw your consent to participate in the study, please contact the

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Study Director:
PD Dr. Claudia Rudroff
Claudia.rudroff@evk-koeln.de

Declaration of consent

.....
Name of the patient in block letters

born ..... Participant no. . .....

The following questions have been discussed with me in detail. I answer them by circling "Yes" or "No".

- I consent to have my biomaterials and data analyzed for research on defecation disorders, including genetic research:
  □ yes □ no
- I agree that my biomaterials and data may be retained for future research, including genetic research, on defecation disordersand analyzed at a later date.
  □ yes □ no
- I consent to my biomaterials and data being used for other genetic research. □ yes □ no
- I agree that my biomaterials and data may be may also be passed on pseudonymously to other researchers, universities, research institutes and research companies for the purpose of research, including genetic research, on defecation disorders.
  □ yes □ no
- My biomaterials and data may be used indefinitely for medical research on defecation disorder
  □ yes □ no
- My biomaterials and data may be used for medical research projects on defecation disorder for up to ten years.
  After that, my biomaterials must be destroyed and the personal data deleted.
  □ yes □ no
- If I no longer wish to participate in the clinical study (revocation)
  my biomaterials and data are to be destroyed. □ yes □ no

- I agree that the results of the examination may continue to be used even if the biomaterials and data are destroyed. .

□ yes □ no

- I would like to be informed personally about the result of the examinations.

□ yes □ no

- I agree that my biomaterials and data, as described in the information document, may be given to the Clinic for General and Visceral Surgery at the Ev. Klinikum Köln Weyertal, and used for medical research purposes.

I received a personal interview by the investigator

.....
Name of the physician

I have been informed in a detailed and comprehensible manner about the nature, significance, risks and implications of the clinical trial. I have also read and understood the text of the patient information leaflet and the data protection declaration printed below. In addition, the explanations on the EU Data Protection Regulation were explained to me and handed out as an additional information document.

I had the opportunity to speak with the investigator about the conduct of the clinical trial. All my questions were answered satisfactorily.

Ability to document additional questions from the patient or other aspects of the educational interview:

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I had enough time to make up my mind.

I am aware that I can withdraw my consent to participate in the study at any time and without giving reasons (verbally or in writing) without any disadvantages for my medical treatment.

_____

Privacy:

I am aware that personal data, in particular medical findings, will be collected, stored and evaluated about me during this clinical study. The use of the data will be in accordance with legal regulations and requires the following voluntarily given declaration of consent before participation in the clinical study, i.e. without the following consent I cannot participate in the clinical study.

1. I consent to personal data, in particular information about my health, being collected about me in the course of this clinical study and recorded in paper form and on electronic data carriers at Ev. Klinikum Koeln Weyertal. If necessary, the collected data may be passed on pseudonymized (encrypted).

2. In addition, I consent to authorized agents bound to secrecy inspecting my personal data held by the investigator, in particular my health data, insofar as this is necessary for the proper conduct of the study. For this measure, I release the investigator from the medical confidentiality obligation.

3. I have been informed that I can terminate my participation in the clinical study at any time. Upon withdrawal of my consent to participate in the study, I have the right to request the deletion of all my personal data stored up to that point.

4. I consent to my data being retained for 15 years after the study has ended or been discontinued. After that, my personal data will be deleted, unless there are legal, statutory or contractual retention periods to the contrary.

5. I consent to health data being collected from or viewed by co-treating physicians to the extent necessary for the proper conduct of the study. In this respect, I release these physicians from the duty of confidentiality. Yes/no

6. I consent to my primary care physician

.....
Name

is informed about my participation in the clinical trial.

I declare myself ready,
to voluntarily participate in the above clinical trial.

I have received a copy of the Patient Information and Consent and the Explanatory Notes on the EU Data Protection Regulation of 2018. One copy remains at the trial site.

.....
Name of the patient in block letters

.....	.....
Date	Signature of the **patient**

I conducted the informed consent interview and obtained the patient's consent.

.....
Name of the investigator in block capitals

.....	.....
Date	Signature of the **investigator** providing the information