Request to participate in medical research:

Correlation of symptoms and ultrasound signs of adenomyosis

Association of ultrasound features of the myometrium suggestive of adenomyosis and clinical symptoms (MUSA 3)

We would like to ask you if you would be willing to participate in our research project.

Your participation is entirely voluntary. All data collected in this research project will be subject to strict data protection regulations.

This research project is conducted under the leadership of Prof. Dr. Gwendolin Manegold-Brauer as National Lead and is carried out at Kantonsspital Winterthur by Dr. med. Teresa Gamper.
We will explain the main points and answer your questions in a meeting. To give you an idea, here are the main elements. Further detailed information will then follow.

Why are we conducting this research project?

- Adenomyosis is a disease of the uterus that causes a range of symptoms (period pain, heavy period bleedings, abdominal pain, etc.) and is difficult to diagnose as it usually requires a tissue sample.
- In our research project, we want to find out whether there is a correlation between the typical symptoms and certain characteristics in the ultrasound exam.

What do I have to do when I participate? - What happens to me if I participate?

- Mode of participation: The ultrasound examination will be the same if you participate in the study or not. There will be no additional intervention or examination. If you decide to participate, we will ask you to answer some questions in a questionnaire to assess your symptoms in detail.
- Procedure for participation: If you participate, we ask you to complete the detailed questionnaire one [1 appointment; duration approx. 10-15 minutes].

What are the benefits and risks involved?

Benefits

- There is no direct benefit to you if you take part in this research project.
- With your participation you can help future patients.

Risk and burden

- The study does not involve any risks for you. Your data will be used in coded form to ensure a high level of data security.

By signing at the end of the document, you confirm that you are participating voluntarily and that you have understood the content of the entire document.

Detailed information

1. Aim and selection

In this information document, we refer to our research *as a* research project. If you take part in this research project, you are a *participant.*

In this research project, we want to investigate whether there are typical ultrasound features of adenomyosis that are associated with the symptoms of the disease. The aim is to use ultrasound to make the diagnosis more reliable in the future. People with or without symptoms can take part. We are inviting you because anyone over the age of 18 who is due for a gynecological ultrasound scan can participate.

2. General information

Adenomyosis is a benign disorder of the muscle of the uterus that can cause painful periods, abnormal bleeding such as heavy menstrual bleeding, abdominal pain and a range of other symptoms. We still know very little about how strong the correlation between certain ultrasound characteristics of the uterine muscle and severity of the symptoms is. If you participate, you will help us to find out how we can better assess the severity of adenomyosis using ultrasound. The research project will be continued over the course of 3 years and we plan to include about 1000 participants in several centers in Europe. In Switzerland, we expect about 400 study participants.

We are conducting this research project in accordance with Swiss law. We are also following all internationally recognized guidelines. The local ethics committee has reviewed and approved the research project.

3. Procedure

You will be asked to take part in the study because you will be scheduled for a gynecological ultrasound scan. You can participate whether you have any symptoms or not, because we also want to examine asymptomatic women. If you decide to take part, you will receive a questionnaire asking you about any symptoms you may have. The focus is on pain and cyclic bleeding. It will take about 10-15 minutes to answer the questions. The ultrasound scan is no different from the routine scan you are scheduled for in any case. The data is collected once and there are no further appointments. Already collected data in your medical history can be used as well. We may cancel your participation, for example, if an exclusion criterion is found or not recognized during recruitment.

4. Benefit

You will not personally benefit from your participation.

5. Voluntariness and obligations

Your participation is voluntary. If you do not want to participate in this research project, or if you withdraw you consent later, you do not have to give any reason. Your treatment/care will be guaranteed regardless of your decision.

6. Risks and burdens

During the research project, you are not exposed to any risks or only minor risks (data risk). Your data will only be used in coded form.

7. Alternatives

If you do not wish to participate in this research project but are open to the possibility of participating in other research projects, please contact your investigator.

8. Results

At the end of the trial, there are objective results for the whole research project. Your investigator can provide you with a summary of the overall results at the end of the research project.

9. Confidentiality of data and samples

9.1. Data processing and encryption

For this research project, your personal and health data will be collected and processed, partly in automated form. Your data will be coded during data collection. Coding means that all reference data that could identify you (name, date of birth, etc.) will be deleted and replaced by a code. People who do not have access to this key list cannot draw any conclusions about your identity. The key list always remains at the Kantonsspital Winterthur.
Only very few specialists will see your uncoded data, and only to fulfill tasks within the framework of the research project. These persons are bound to confidentiality. As a participant, you have the right to view your data.

9.2. Data protection and sample protection

All data protection requirements will be strictly adhered to. Your data may have to be transferred in a coded form, e.g. for a publication, and may be made available to other researchers. The sponsor is responsible for ensuring that the same standards are maintained abroad as in Switzerland.

9.3. Data protection for further use

Your data and samples may be important for answering other questions later and/or may be transferred to another database in Switzerland or abroad for not yet specified research purposes (further use). These other databases must meet the same standards as the database for this project. For this re-use, please sign another consent form at the end of this document if you agree. This second consent is independent of your participation in this project.

9.4. Inspection rights during controls

This research project may be reviewed by the local ethics committee and project management. The investigator will then have to disclose your data for these reviews. Confidentiality will always be ensured during any reviews or inspections.

10. Withdrawal

You can withdraw your participation in the research project at any time. In this case, the data and samples collected so far will still be analyzed in coded form. If you withdraw, your data and samples will remain coded in the project documents. This is for your medical security. Please check if you agree to this before participating in the project.

11. Compensation

You will not receive any compensation for taking part in this research project.
There will be no cost to you or your health insurance company. The results of this research project may contribute to the development of commercial products. Participation does not give you any rights to commercial developments (e.g. patents).

12. Liability

If you suffer damage because of the research project, the Kantonsspital Winterthur, which participates in the research project and is responsible for carrying out the project, is liable. The requirements and procedures are regulated by law. If you have suffered damage, please contact the investigator.

13. Financing

The research project is organized by the University Hospital of Basel. Research funding will be sought from private and public foundations that offer research funding.

14. Contact person:
You can always ask questions about participating in the project. Please contact us if you have any questions during or after the research project:

Name:	Dr. med. univ. (A) Teresa Gamper
Address:	Kantonsspital Winterthur Frauenklinik Brauerstrasse 15, Postfach 8401 Winterthur
E-Mail:	frauenklinik.ambulatorium@ksw.ch
Phone (24 /7r) :	+41 52 266 3030

Declaration of consent

Written consent to participate in a research project
Please read this form carefully. Please ask if there is anything you do not understand or would like to know more about. Your written consent is necessary for your participation.
Your written consent is required for participation.

BASEC number:	2023-01484
Title of the research project (scientific and lay language):	Association of ultrasound features of the myometrium suggestive of adenomyosis and clinical symptoms (MUSA 3) Correlation of symptoms and ultrasound signs of adenomyosis
Responsible institution (project lead with address):	Prof. Dr. Gwendolin Manegold-Brauer Department of Gynecological Sonography and Prenatal Diagnostics, Women's Clinic, University Hospital Basel, Spitalstrasse 21, 4031 Basel
Place of execution:	Kantonspital Winterthur
Head of the research project at the place of study: Surname and first name in capital letters:	Dr. med. univ. (A) Teresa Gamper
Participant: Surname and first name in capital letters: Date of birth:	

- I have been informed orally and in writing by the undersigned investigator(s) about the purpose, conduct, possible benefits, disadvantages, and risks of the research project.
- I am voluntarily participating in this research project and accept the content of the written information provided for the above research project. I have had sufficient time to make my decision.
- My questions about my participation in this research project have been answered. I will keep the written information and receive a copy of my written consent.
- I agree that my uncoded data may be inspected by the experts responsible for project management and the ethics committee responsible for this research project for testing and control purposes, but under strict adherence to confidentiality.
- I understand that my health-related and personal data can only be transferred in coded form for research purposes for this research project (including abroad). The sponsor guarantees that data protection according to Swiss standards will be maintained.
- I can withdraw from the study at any time without giving reasons. My further treatment is guaranteed regardless of my participation in the research project. The data collected so far will continue to be used for the evaluation of the research project.
- The Kantonsspital Winterthur is liable for any damages.

Place, date	Signature of participant

Confirmation by the investigator: I hereby confirm that I have explained the nature, importance and scope of the research project to this participant. I assure you that I will comply with all obligations under Swiss law relating to this research project. If, during the course of the research project, I become aware of any aspect that might influence the participant's commitment to the research project, I will inform him/her immediately.

Place, date	Name and first name of the investigator in capital letters Signature of the investigator

Declaration of consent for further use of data for further use of data of this research project in coded form

BASEC number (after submission):	2023-01484
Title of the research project (scientific and lay language):	Association of ultrasound features of the myometrium suggestive of adenomyosis and clinical symptoms (MUSA 3) Correlation of symptoms and ultrasound signs of adenomyosis
Participant Surname and first name in capital letters: Date of birth:	

- I allow my encrypted data from this research project to be used for medical research, for future, yet undefined research projects for an indefinite period of time.
- I understand that the data are coded, and the key is kept safe. The data can be sent to other national or international databanks for analysis if they comply with the same standards as in Switzerland. All legal requirements for data protection are complied with.
- I decide voluntarily and can withdraw this decision at any time. If I withdraw, my data will be anonymized. I only inform my investigator and do not have to justify this decision.
- All data are evaluated as a whole and the results are published in summary. If there is an important result for my health, it is possible that I will be contacted. If I do not wish this, I will inform my investigator.
- If applicable with anonymization: I allow my data and samples to be anonymized and have understood that in this case, I cannot be informed about random results or withdraw from the research project.
- If results from the data and samples are commercialized, I am not entitled to share in the commercial use.

Place, date	Signature of participant

Confirmation from the investigator: I hereby confirm that I have explained to this participant the nature, meaning and scope of the further use of data.

Place, date	Name and first name of the investigator in capital letters Signature of the investigator