Patient information and informed consent form

Recording of deliveries in patients with deep endometriosis

Hello,

we invite you to participate in the register study "Birth register for deep endometriosis".

Your participation in this study is voluntary. You can withdraw from the study at any time without giving reasons. Refusal to participate or premature withdrawal from this study will not have any adverse consequences for your medical care.

The Ethics Committee of Upper Austria issued a positive opinion on this register study.

1. What is the purpose of this study?

The purpose of this register study is to collect data on deliveries in women with deep endometriosis. Deep endometriosis (DE) has a special place in the clinical picture of endometriosis. It is defined as solid endometriosis lesions with a depth of infiltration of ≥ 5 mm and is associated with a significantly higher morbidity than the more frequent superficial endometriosis of the peritoneum. The results of this survey should help to provide better advice to affected women during pregnancy regarding the mode of birth and individual risks.

2. How does the register work?

No special measures will be taken solely for reasons of study participation.

This register study is being conducted at several study sites.
If all inclusion criteria for the study are met, you will be asked whether you would like to participate in the study. If you agree to participate in the study, facts about your delivery as well as details on your endometriosis disease will be entered into a database in a pseudonymised form.

3. What are the benefits of participating in this register study?

It's not expected that you gain directly health benefits from your participation in this study, but future patients in the same situation may benefit from the results.

4. Are there any risks, complaints or side effects?

No.

5. Data protection

With regard to the data that is collected about you in the context of this register study, a basic distinction must be made between

1) those personal data by which you can be directly identified (e.g. name, date of birth, address, pictures taken...),
2) pseudonymised (encrypted) personal data, in which all information that allows direct conclusions to be drawn about your identity is replaced by a code (e.g. a number) or (e.g. in the case of image recordings) made unrecognisable. This has the effect that the data can no longer be assigned to your person without consulting additional information and without disproportionate effort, and
3) anonymous data, where a traceability to your person is no longer possible.

The code for encryption is strictly separated from the encrypted data records and is kept only at your trial site.

Access to your unencrypted data is available to the investigator and other study center staff involved in the register study or your medical care. The data is protected against unauthorized access. In addition, authorized representatives of the sponsor (Kepler University Hospital, University Clinic for Gynecology, Obstetrics and Gyn. Endocrinology) who are sworn to secrecy as well as representatives of domestic and/or foreign health authorities and the respective competent ethics commissions may inspect the unencrypted data to the extent that this is necessary or prescribed for the verification of the proper conduct of the register study.

The data will only be passed on in an encrypted or anonymous form. Also for any publications only the encrypted or anonymized data will be used.

All persons who gain access to your encrypted and non-encrypted data are subject to the European Data Protection Regulation (DSGVO) and the Austrian adaptations in the respective valid version.

No data transfer to countries outside the European Union is foreseen in this register study.

You can revoke your consent to the collection and processing of your data at any time. After your revocation, no further data about you will be collected. However, the data already collected until revocation can still be used within the scope of this register study.

Furthermore, in accordance with the law, unless this is likely to make it impossible or seriously affect the performance of the register study, you also have the right to access the data concerning you and the possibility of correction if you discover errors.

You also have the right to lodge a complaint to the Austrian data protection authority regarding the handling of your data (www.dsb.gv.at).

The expected duration of the study is not fixed, as the present study is a register study. The duration of the storage of your data beyond the end of the study is regulated by legal provisions.

If you have any questions regarding the handling of your data in this register study, please contact your investigator first. If necessary, he or she can forward your request to the persons responsible for data protection.

6. Possibility to discuss further questions including questions on data protection

If you have any further questions in connection with this study, please do not hesitate to contact your study physician.

Names of the contact persons: Dr. Christina Allerstorfer, MSc.; Dr. Simon-Hermann Enzelsberger, MSc.

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Data protection officer		**Data protection supervisory authority**	
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7. Declaration of informed consent

Name of patient: ..... Date of birth: .....
(in block letters)

I agree to take part in the register study "*Birth register for deep endometriosis*".

Mr. / Mrs. ..... have informed me in detail and in a comprehensible manner about the register study, possible burdens and risks, as well as about the nature, meaning and scope of the register study, and the requirements resulting from it for me. I have also read the text of this patient information and consent form, which is 3 pages long. Any questions that arose were answered in a comprehensible and sufficient manner. I had sufficient time to decide to participate. I have no further questions at the moment.

I will follow the medical orders required for the register study, but reserve the right to terminate my voluntary participation at any time without prejudice to my further medical care.

I expressly agree that my data collected in the context of this register study may be used as described in the "Data protection" section of this document.

I have received a copy of this patient information and informed consent form. The original remains with the study doctor.

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(date and signature of patient)

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(date, name and signature of the responsible doctor)