INFORMATION FOR PATIENT ABOUT PARTICIPATION IN REASEARCH PROJECT:

Pregnancy-related hysterectomy

" PREGNANCY-RELATED HYSTERETOMY: A CASE-CONTROL POPULATION-BASED STYDY AMONG 12 COUNTRIES OF THE INTERNATIONAL NETWORK OF OBSTETRIC SURVAY SYSTEMS"

We want to ask you to participate in a study. In this document you can find information about the project, how participating in this project affects you and how to be excluded from the project if you do not wish to take part (opt-out). If you don´t request that information about you or your newborn child to be removed, you will be included in the study. All legal guardians have the right to request an opt-out for the part concerning the child, only the person who was pregnant can opt out of the part concerning the pregnancy. We would like to hear from you within 4 weeks of this letter being sent if you wish to be exluded. If we do not hear from you within this time, you and your newborn child will be included in the study.

What is this project and why should you participate?

The international network of obstetric survey systems (INOSS) is conducting a research project on pregnancy-related hysterectomy (removal of the uterus). INOSS is a multinational collaboration of organizations conducting studies of serious illnesses in pregnancy and childbirth. Many severe complications of pregnancy are uncommon and therefore difficult to study on national basis. The purpose of this project is to examine and compare the rate of pregnancy-related hysterectomy in participating countries. Pregnancy-related hysterectomy is performed as a life-saving intervention in cases of potentially lethal bleeding when other treatments fail. In Sweden, approximately 60 women undergo a pregnancy-related hysterectomy each year. Examining the rate of pregnancy-related hysterectomy is a good way to evaluate the quality of care in participating countries, and contributes with valuable information which could improve the care of future women and children.

In order to improve the quality of care of women in need of pregnancy-related hysterectomy, your clinician send anonymous health data from your medical records in a specific collection form and to research personnel. Data will also be collected from national quality registers (Swedish Intensive Care Registry, The Swedish Pregnancy Register, Statistics Sweden and The Swedish Perioperative Register). Your clinician is responsible for reporting your personal data to these national quality registers. Data from national quality registers will also be sent anonymous to research personnel. The code key, which links your social security number with a serial number in the project, will only be available at SCB and will not be accessible to the researchers. The key-code will be destroyed after 3 years.

Your healthcare provider is responsible for reporting data to these quality and health registers. All data we collect is without social security numbers to make it impossible to trace the data back to the individuals included in the study.

Entity responsible for the research is Västra Götalandsregionen. Principal investigator in Sweden is Teresia Svanvik, Västra Götalandsregionen (Contact information below).

Why have you been given this information?

You have undergone a pregnancy-related hysterectomy **OR** you have been chosen as part of the control group that have not undergone a hysterectomy.

By participating in this research project," PREGNANCY-RELATED HYSTERETOMY: A CASE-CONTROL POPULATION-BASED STYDY AMONG 12 COUNTRIES OF THE INTERNATIONAL

NETWORK OF OBSTETRIC SURVAY SYSTEMS", you will contribute with valuable information which could improve the care of future women who undergo or are at risk of undergoing pregnancy-related hysterectomy. Your participation in this project is voluntary and will not affect the health care you receive. The health data collected will be used to compare the care given when undergoing pregnancy-related hysterectomy in Sweden with other participating countries. The result will be used to improve the care of future women and children. The more participants, the more certain the result.

Procedure

Health data regarding your pregnancy, delivery and newborn child will be collected in a specific data collection form by your clinician and by research personnel. This data collection form is similar in all participating countries. Health data will also be retrieved from Statistics Sweden and national quality registers; Swedish Intensive Care Registry, The Swedish Pregnancy Register and The Swedish Perioperative Register. Data collected from women that have undergone a pregnancy-related hysterectomy in Sweden will be processed and then compared to processed data from other participating countries and to a control group (pregnant women that have not undergone a pregnancy-related hysterectomy). Only de-identified data on group-level will be compared to the data from other participating countries.

Data management

Health data regarding you, your pregnancy, your delivery and your child will be collected. Identifying information will be replaced by a serial number before sending to the investigators, the key-code will be stored separately from any names or social security number. The identifying information (key-code) will only be available for your clinician and SCB and will not be shared with investigators in Sweden or internationally. Data will be shared in aggregated form with the international researchers to compare differences between participating countries. This means that it will be shared at a group level, making it impossible to identify individual participants.

Security

Information regarding you and your newborn child will be kept confidential and not be shared with unauthorized persons. Solely research personnel will have access to coded data in order to process and analyze. The data collected for the purposes of the study will be processed in accordance with all applicable laws and regulations. No unauthorized parties will have access to your health data. The coded data will be processed and kept in a locked safe at Sahlgrenska University Hospital. Only research personnel will have access to the coded data. The coded data will be shared with a statistician in order to carry out statistical analyses. The key-code will be kept at your healthcare provider and at Statistics Sweden, it will not be available to investigators. The study results will be shown in anonymous and/or aggregate form and the parties involved will not be identifiable. The key-code will be destroyed in 3 years. All data will be presented at group-level (no data will be presented for groups with fewer than five individuals), it will not be possible to identify participating individuals.

Laws and regulations

Anyone processing personal data must rely on a legal basis and adhere to fundamental principles in accordance with the General Data Protection Regulation (GDPR). More information about the GDPR can be found on the Swedish Authority for Privacy Protection's website (https://www.imy.se/verksamhet/dataskydd/det-har-galler-enligt-gdpr/)."

Processing of personal data and data from registers must be carried out in accordance of laws and regulations (i.e. the regulations on protection of personal data "7 kap. patientdatalagen (SFS 2008:355)".).

Confidentiality

Your personal health- and medical data is confidential in accordance of Public Access to Information and Secrecy Act (SFS 2009:400). This means that your personal information can only be disclosed from registers and medical records if it is clear that neither you nor anyone close to you risk any harm by doing this.

Risks

This project does not pose any risk of physical harm, pain or discomfort for participating women. The project is based on data from medical records and national quality registers.

Some data from medical record and registers might be of sensitive character, however, the information collected will be coded and not be identifiable, the study results will be shown in anonymous form. All data will be presented at group-level and no data will be presented for groups with fewer than five individuals.

Rights

- You have the right to withdraw your personal information from the study. To do this, contact the principal researcher listed below.
- If you chose not to participate or discontinue your participation you do not need to state a reason and it will not affect your future medical care in any way.
- You have the right to receive information about which care unit and at what time someone had access to your data.
- You have the right to compensation if the personal data is handled in violation of the Data Protection Regulation or the Public Access to Information and Secrecy Act.
- You have the right to file a complaint with the supervisory authority. According to the EU's data protection regulation, you have the right to receive information about you that is handled in the study, free of charge, and to also be able to have any incorrect information corrected. You can also request that data about you be deleted.

Contact information

If you want more information about the project, access to your data, request correction, restriction or request that all your data be removed from the database for the project" PREGNANCY-RELATED HYSTERETOMY: A CASE-CONTROL POPULATION-BASED STYDY AMONG 12 COUNTRIES OF THE INTERNATIONAL NETWORK OF OBSTETRIC SURVAY SYSTEMS" please contact principal investigator Dr. Teresia Svanvik (contact information listed below).

The data protection officer at Sahlgrenska University Hospital can assist you in obtaining information about you that is handled in the study and can be reached at the address Sahlgrenska University Hospital, data protection officer, 413 45 Gothenburg or telephone 031-343 2715.

If you are dissatisfied with how your data is processed, you have the right to lodge a complaint with the The Swedish Authority for Privacy Protection's (IMY), which is the supervisory authority. Information is available on the The Swedish Authority for Privacy Protection's website https://www.imy.se/en/.

Additional information about the national quality registers can be found at https://www.kvalitetsregister.se/en/kvalitetsregister/omnationellakvalitetsregister.52218.html.

Principal investigator

Sweden

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