INFORMATION FOR THE PATIENT AND CONSENT FORM

Study: *Multicentric registration study regarding preservation of fertility in young women with cancer.*

Introduction

Dear Madam,

You are invited to participate in a clinical study aiming to map out the issues regarding preservation of fertility in young women undergoing cancer treatment.

This study focuses on all women diagnosed with cancer who want to preserve their fertility. A control group (young women diagnosed with cancer who received the standard treatment) is necessary to be able to answer the scientific questions about this subject.

It is important that you understand why this research is performed and what it incudes, before you decide whether or not you want to participate. Take enough time to read the following information thoroughly and, if desired, to discuss this with family, friends or your general practitioner. Ask your research doctor or nurse for more information if something is not clear or if you require more information. Only decide whether or not you want to participate after thorough consultation. This study has been investigated and approved by the ethical committee of the university hospital of Leuven.

More information about the study is available on the following website: www.cancerinpregnancy.org

What is the purpose of this study?

Fertility sparing cancer treatments are treatments that deviate from the standard treatment in the sense that the alterations are focused on preservation of fertility. An example can be an operation for cervical cancer with removal of only the cervix instead of the entire uterus or removal of a part of the ovary in ovarian cancer or freezing oocytes or embryos before starting cancer treatment. Since fertility sparing cancer treatments are not so frequently performed, there is insufficient knowledge about the treatment and outcome of women who undergo such treatment. The purpose of this study is to map out the issues regarding fertility preservation during and after the cancer treatment. By registering both women who undergo fertility sparing cancer treatments and women who undergo the standard treatment, we can investigate and compare the outcome of both. Together with this we want to investigate if women who undergo fertility sparing cancer treatments, experience more problems getting pregnant and during pregnancy. This way we can obtain a better insight in these problems and the outcome of these women.

Description of the study

Within the framework of this study, we will as precisely as possible record your medical data with respect to the diagnosis, the treatment and the outcome on the basis of your medical file. If applicable we will register your following pregnancy(ies) and the general condition of your child. In order to do so, we would like to ask your permission to reclaim information about your medical file from your family doctor.
You do not need to undergo any extra procedures for this study.

Your participation is voluntary

It is up to you to decide if you want to participate or not in the study. If you give your consent for participation, you will be asked to sign the attached consent form. You can revise your decision at any moment without any specific reason. If you decide to not take part or to discontinue your participation, this will not have any influence on the quality of your current or future medical care and you will not lose any benefits you are normally entitled to.

Advantages and disadvantages of your participation in this study

Taking part in this study will not lead to personal advantages but it can help to obtain useful scientific information for the future. There are no disadvantages, risks or discomfort expected when participating in a registration study.

Confidentiality and data protection

The information that will be obtained about you will be handled with complete discretion and will only be used for this study. Your treating doctor is responsible for the protection of the data. In order to protect your identity, your personal information and other data that are obtained from the study will be identified by means of a unique number. Your name will not be mentioned in publications or reports of this study.
If you want to discontinue your participation in this study, no additional data will be collected. The information that has been collected until then, however, will be used for analysis.

Under strict conditions, direct access to the medical file can be granted to authorised personnel of the principal (UZ Leuven via prof. F. Amant) or of his representative(s), to regulatory authorities or to other persons who are authorised by law to check if the research is being carried out correctly. Access is only granted to examine the quality of the collected data, so it will not be granted systematically.

Direct access to the medical file by third parties will exclusively be granted in the presence and under responsibility of the supervising researcher or fellow researchers.

Everyone who has access to the medical file is bound to the professional secrecy.

The participant always has the right to ask the researcher about the data that are being collected for the study as well as the purpose of this data. She also has the right to get insight in her personal information through the researcher and, if needed, to make alterations.

All personal information and other data will be treated and processed in accordance with EU regulation 2016/679 and the Belgian legislation on the protection of natural persons with regard to the processing of personal data.

If you have further questions about data protection, please do not hesitate to contact the Data Protection Officer of UZ Leuven: gdpr.research@uzleuven.be.

You have the right to lodge a complaint about how your information is treated with the Belgian supervisory authority responsible for enforcing data protection legislation: Data Protection Authority (DPA), Rue de la Presse 35, 1000 Brussels, +32 2 274 48 00, contact@apd-gba.be, www.dataprotectionauthority.be

Data retention period

Your data must be stored for 20 years at the research location and 20 years at the principal, Prof. Amant, UZ Leuven.

Data storage and use for other research

After this study, your data may also be of importance for other scientific research in the area of cancer and fertility. To enable this, your data will be stored for 20 years. You can indicate on the consent form whether or not you agree with this. If you do not agree, you can still take part in this study.

Approval by the central and local committees

This study has been approved by an independent ethical committee (Committee for Medical Ethics of UZ Leuven, which functions as central committee for this project). This study will be performed according to the guidelines for good clinical practice (ICH/GCP) and according to the most recent version of the declaration of Helsinki drawn up to protect people participating in clinical studies. Under no circumstances do you need to consider the approval of the Committee for Medical Ethics as an encouragement to participate in this study.

General practitioner

Your family doctor and treating specialist(s) will be informed of your participation.

Expenses and reimbursement for the patient

Since this is a non-sponsored study you will not be compensated for your participation. There is no reimbursement available by a medical firm, nor for the investigating doctor, nor for the department of the hospital.

Insurance

In accordance with the Belgian Act of May 7, 2004 regarding experiments on humans, the principal is, even if free from errors, accountable for any damage suffered by the participant or his beneficiaries if this is directly or indirectly caused by the experiment. The principal of this study has concluded an insurance that covers this liability. Should you suffer damage as a result of your participation in this study, this damage will subsequently be compensated in accordance with the Belgian Act of May 7, 2004.

As participant in this study you are covered by the insurance policy closed by the Catholic University of Leuven with insurance broker Vanbreda risks & benefits nv, located at Plantin en Moretuslei 297, 2140 Antwerpen, Belgium, with policy number 299.053.700. You can find a copy of this insurance policy and its conditions with your person responsible of the study.

Contact persons in case of questions about the study

Should you have questions about the study now or during your participation, please do not hesitate to contact:

Katrien Van Tornout (case manager)

Department of Obstetrics & Gynaecology

Telephone 016/34.2876

Prof. Dr. Frederic Amant (head of research)

Department of Obstetrics & Gynaecology

Telephone 016/34.4252

Thank you in advance,
The research team

INFORMATION FOR THE PATIENT AND CONSENT FORM

Study: Fertility sparing treatment in young women with cancer

- I confirm that I have read the previous pages of the consent form. I confirm that I received sufficient information about the study and the investigations related to the study.
- I confirm that I have had the opportunity to ask questions about this study and that I received satisfying answers and explanation.
- I confirm that I have had enough time and opportunities to read the information carefully, to discuss with others and to decide whether or not I want to participate in this study.
- I understand that I will receive a signed copy of this consent form.
- I grant access to my original medical file to the following persons/organisations: the treating doctor, the head of research and his/her colleague(s), the ethical committee of the hospital and the competent regulatory public bodies.
- By signing this form I do not waive the legal rights I am normally entitled to as participant in a study.
- By signing this form I voluntarily agree to participate in this study.
- I **do/don't*** give permission to store my personal data for longer and to use it for future research in the area of cancer and fertility. My data will be stored at the research location for 20 years.
- In the future, researchers **may/may not*** approach me for similar research.
- I **do/don't*** give permission to the researchers to use my contact details in the framework of this study.

  *** Please delete what is not applicable**

Signature of the patient	Date
Name of the patient, in capitals	
Signature of the person getting the consent	Date
Name of the person getting the consent, in capitals	