

INFORMATION FOR THE PATIENT AND INFORMED CONSENT DOCUMENT

Patiënt ID: _____

Study: Multicentre study on cancer during pregnancy: registration study, study on the psychological impact of cancer diagnosis during pregnancy, study on pharmacokinetics of chemotherapeutical agents during pregnancy and on the effects of chemotherapy and/or radiotherapy on mother and child.

Title: Long term follow up of children who were in utero exposed to chemotherapeutic agents and/or radiotherapy. Authorization of the child at the age of 14years.

Introduction

As you already heard from your parents and physician, we follow your health and development because your mother was treated with chemotherapy and/or radiotherapy for a malignant disease during pregnancy.

Earlier your mother agreed for your participation in this study. At that moment it was stated that at the age of 14 years you would be asked to confirm your further participation.

Before you make your decision to participate, it is important that you understand why this research is done and what it all includes. Take your time to read the following information carefully and if required, discuss it with friends, family or your general practitioner. Ask the study physician or study nurse for more information if something is not clear or you want more information. Decide after thorough consultation if you want to take part yes or no.

This study is reviewed and approved by the ethical committee of the hospital.

The aim of the study

The aim of the study is to examine whether the chemotherapy and/or radiotherapy given to your mother during pregnancy has an effect on your health and development. By participating in this study, you help researchers to enlarge current knowledge and make it possible to inform future patients better.

Description of the study

The examination previously performed, will be planned 3-yearly until you are 18 years old.

On the day of the examinations you will be weighed and your height will be measured. Thereafter, a neuropsychological examination will be planned. You will be asked to do some tests (remember a list of words and figures, computer tasks, bringing associated figures together,).

Those tests are already done in many children of your age. Therefore it is possible to compare your results with those of other children of your age.

Furthermore a cardiological examination will be performed. The pediatric cardiologist will examine you (listening with a stethoscope), an electrocardiogram will be taken (some small adhesive patches will be attached on your chest and a device records the electrical signals from your heart). Afterwards and ultrasound of your heart will be done (with some gel and a probe on your chest the rooms and the valves of your heart will be examined)

Your participation is voluntary

It is your choice whether or not to participate in this trial. If you want to take part, you will be asked to sign the informed consent page. You will receive a signed and dated copy of this written approval. You can reconsider your decision at every moment without giving a specific reason.

If you decide not to participate or to stop your participation in the study, this will not affect the quality of your treatment or your medical treatment in the future. You will not lose advantages you are entitled to.

Reimbursement and compensation for the patient

There is no compensation from a medical company, nor for the researchers, nor for the hospital department.

Since this study is not sponsored, you cannot receive any compensation for taking part.

Confidentiality and protection of data

The information which is obtained concerning your person will be handled as confidential information and will only be used for this study. Your physician is responsible for the protection of the data. To protect your identity, your personal information and data that result from the study will be identified by a unique number. Your name will not be mentioned in publications or reports from this study.

You have the right to ask your physician which data are collected in this study and for which purpose. You also have the right to access your medical file.

Contact person in case of question

If you may have questions about the study, now or during your participation, you can always contact:

Study physician _____ Telephone: _____

Study nurse: _____ Telephone: _____

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- I confirm that I have read the previous pages of the informed consent document. I confirm that I had a satisfying explanation of the study and the examinations that will be performed for this study.
- I confirm that I have had the possibility to ask questions concerning the study and that I received satisfying answers.
- I confirm that I had enough time to read the information attentively, to discuss it with others and to decide whether or not to participate in this trial.
- I understand that I will receive a signed copy of this informed consent document.
- I give access to the following persons/organisations to my medical files: physician, the person responsible for this study and his employees, the ethical committee of the hospital and the competent regulatory government agencies.
- By signing this form I do not renounce the legal rights on which I can normally claim as a participant of a research study.
- By signing this form I agree voluntarily to take part in this study.

Name patient, in capitals

Date

Signature of patient

Name of the person who obtains the consent, in capitals

Date

Signature of the person who obtains the consent