

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 mother for child

Introduction

As explained by your physician, the malignant disease you are diagnosed with requires chemotherapeutic and/or radiotherapeutic treatment. You have been asked to participate in this clinical research study with the aim to examine whether chemotherapy and/or radiotherapy has an impact on the outcome of mother or child.

Before you decide whether or not to participate, it is important that you understand why this research is performed and what it 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 coordinator or study nurse for more information if something is not clear or if you want more information. Decide after thorough consultation whether or not you want to participate.

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

Description and aim of the study

The aim of the study is to follow the development of your child by clinical examination, ultrasound of the heart and a neurological examination (questionnaires, tests for intelligence and motor development). No blood samples will be taken. Short after birth, your child will be examined by a pediatrician. At the age of 18 months, 5-6year, 8-9years, 11-12years, 14-15years and 17-18years, you will be invited to the hospital for the examinations.

We ask your permission to follow your child in this way. At the age of 14, your child will be asked if it still wants to participate in this trial.

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 of the parent (in capitals)

Date

Signature of the parent

Signature of the person who obtains the consent

Date

Signature of the person who obtains the consent (in capitals)