

INFORMATION FOR PATIENT AND INFORMED CONSENT DOCUMENT

Patient 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: Effect of chemotherapeutical agents on the pregnancy: distribution of chemotherapeutic agents in the body and evaluation of the effect of chemotherapeutical agents on mother and child.

Introduction

As explained by your physician, the malignant disease you are diagnosed with requires chemotherapeutic treatment. You have been asked to participate in this clinical research study with the aim to examine whether chemotherapy has an impact on the outcome of mother or child. Further, this study will also test the distribution of chemotherapeutical agents in the body of a pregnant women.

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.

The aim of the study

The aim of the study is to examine whether the distribution of chemotherapeutical agents differs between pregnant and non-pregnant patients. This study examines whether chemotherapy administered during pregnancy causes other or more severe problems compared to non-pregnant patients.

The determination of the treatment you will receive is not influenced by the study. Other drugs that you may receive (e.g. against nausea) and the care in the hospital you get are part of your normal treatment and are not part of this study.

What is chemotherapy?

Chemotherapy is a drug treatment aiming to eliminate fast dividing cells and is used in the treatment of malignant diseases. These drugs do not only attack malignant cells, but also healthy cells. For example, the production of red and white blood cells and blood platelets can be reduced.

In many patients, chemotherapy induces nausea, possibly with vomiting, for which the appropriate drugs will be given.

Description of the study

Chemotherapy will be administered as in normal standard of care. The only difference will be that immediately before and at specific moments after the chemotherapy, different blood samples will be taken through the intravenous lock system. This system makes it possible to take different blood samples without being punctured every time. A maximum of 50 mL blood will be collected per chemotherapy cycle.

Drugs that are given to reduce the side effects of the chemotherapy can be administered in a normal way during this study.

When your physician decides you can return back home after the administration of the chemotherapy, weekly blood samples will be planned to evaluate how your body tolerates the chemotherapy. These blood samples are often also taken without the participation in this trial.

If your body appears to tolerate the chemotherapy badly, more frequent blood samples may be needed at that moment.

During your pregnancy, monthly a prenatal ultrasound will be performed to evaluate the growth and development of the child.

After your child and the placenta are born, the placenta will be examined thoroughly. A few samples (placenta and umbilical cord blood) will be taken for further research. The paediatrician will perform a thorough physical and standard neurological examination and an ultrasound of the heart. A blood sample will be taken to evaluate the impact of the chemotherapy on your child.

Possible inconveniences and risks

Taking the different blood samples after administration of chemotherapy will be the most important inconvenience during this study.

As already said, an intravenous lock system will be placed so all blood samples can be taken by one puncturing.

All blood samples taken in between the different cycles of chemotherapy, the evaluations of the unborn child by ultrasound and the blood sample taken from your child after birth would probably also be performed without participation in this study.

The biopsy taken from the placenta is taken after birth and does not affect your own well being or the well being of your child.

Possible benefits

If you agree to take part in this trial, this may have an extra medical benefit for you. By your participation in this trial, there will be a thorough medical follow up of your own medical condition and that of your child.

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: _____

INFORMED CONSENT DOCUMENT FOR THE PATIENT

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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.

Signature patient

Date

Name patient, in capitals

Signature of the person who obtains the consent

Date

Name of the person who obtains the consent, in capitals