

# English Patient Information and Informed Consent

## *Simply Capecitabine for Rectal cancer after Irradiation Plus TME*

### SCRIPT STUDY

Recently you have been operated for a malignant rectal tumour. Before the operation you have been irradiated or you have been irradiated and received chemotherapy at the same time. Your surgeon has performed a new operation technique which has been introduced a few years ago in which a larger part of the surrounding tissue with lymph nodes is removed and nerve vessels are spared. This technique, developed to reduce the risk of a recurrence of disease, is called "TME (Total Mesorectal Excision) with nerve sparing".

#### **Aim of the study.**

The aim of the SCRIPT study is to investigate whether the addition of chemotherapy to pre-operative radiotherapy or radiotherapy in combination with chemotherapy and TME surgery (experimental treatment) can improve survival and decrease the risk of recurrence of disease compared to pre-operative radiotherapy or radiotherapy in combination with chemotherapy and TME surgery (standard treatment). A possible effect of chemotherapy on survival in combination with TME surgery and preoperative irradiation or radiotherapy in combination with chemotherapy has never been investigated before.

#### **Content of the study.**

You have been diagnosed with an advanced stage of the tumour or with tumour cells in lymph nodes, which in principle, have been fully removed. Herewith we would like to ask you if you will participate in this trial. This implies that randomisation will determine whether you will receive chemotherapy after surgery or not.

If you randomise for chemotherapy, treatment will start within 6 weeks after surgery. The chemotherapy consists of taking tablets on a daily basis during 14 days after which 7 days of rest follow. Then there is again a period of 14 days of medication and 7 days of rest. This cycle will be repeated 6 more times, which makes the total duration of chemotherapy 24 weeks. Treatment will occur on a out-patient basis. Also in the SCRIPT trial, your quality of life will be studied. In this manner, we will investigate what the effects of chemotherapy will be on the quality of life. For this purpose, questionnaires will be sent prior to the start of chemotherapy, during the chemotherapy, at the end of chemotherapy and six months after the completion of the

chemotherapy. Also, if you do not receive chemotherapy, questionnaires will be sent you.

The treatment for your tumour is performed in an international study, coordinated from the Leiden University Medical Center in The Netherlands. Other hospitals in The Netherlands and Scandinavia are also participating. It is possible that the investigators at some point in the study will ask your surgeon for a part of the tumour for additional research.

**Side effects**

The chemotherapy can cause side-effects, like diarrhoea, inflammation of the mouth, nausea and hair loss, and a decrease in the number of immune cells and blood platelets in blood which can lead to postponement of the chemotherapy treatment. Also, a "Hand-Foot" syndrome may occur, with tingling of the palm of the hands and the foot soles, that may also become numb, painful swollen and/or red. However, these side effects are mostly temporarily.

**What do we expect from you?**

We ask you if you are willing to participate in this study. This means that it will be determined *by draw* whether you will receive chemotherapy after surgery or not. This means that you cannot choose to have chemotherapy or not.

**Voluntary participation**

Obviously you may refuse participation in this trial. Once entered in this study, you are always free to withdraw your participation and of course this will not change the care received from your surgeon. If you do not participate, you are treated according to the standard methods in your hospital.

**Confidentiality of data**

All information that will be gathered during this study, will be kept in confidence and processed anonymously.

**Questions**

If you have any further questions regarding your treatment or the study, please ask your doctor.

Your treating physician: .....

Telephone: .....

**INFORMED CONSENT FORM SCRIPT STUDY**

I have read and understood the patient information concerning the SCRIPT study (of which I got a copy) and I have had the opportunity to ask questions. I have understood the answers and these answers were clear.

I confirm that I had time to think about it and that I have consented to receive possibly chemotherapy after surgery, and I know that I can at any moment:

- ask for more information from my doctor
- stop my participation in the study and that this will not influence the care given to me

I understand that if I want to stop my participation in the study, I do not have to tell why, unless this is caused by toxicity from chemotherapy. In this case, I will inform my doctor.

I allow that my doctor may give information to my general practitioner concerning my participation in this study and other information which might be important. In addition, I allow that he might ask information about my current or past illnesses and treatment.

I understand that my name will not appear in any report. However, I understand that it is important that the study coordinator should be able to look at the medical file to check study-related data. They will not be used for any other purpose.

I agree to participate in the study.

Name patient ..... Signature.....

Date ..... / ..... / .....

Name doctor ..... Signature.....

Date ..... / ..... / .....