

Information sheet for patients related to possible participation in the SPIES bladder cancer study

Title of the study

“SPIES bladder cancer study”:

A multicenter international randomized controlled study to compare the outcome using the Storz Professional Image Enhancement System (SPIES) versus White Light Imaging (WLI) during TURB of Non-Muscle-Invasive Bladder Cancer (NMIBC).

Introduction

Dear Sir/Madam,

You are being invited to participate in a research study with the title ‘SPIES bladder cancer study’. You are being approached because you probably have bladder cancer. Your doctor and you agreed to the necessity of surgical removal of this tumor. You decide if you want to participate in this study. If you participate in another study at the moment, you cannot participate in this study. Before you decide if you want to take part, it is important to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with your partner, family or friends. You can also inquire about this study by the independent physician, who knows a lot about this study, but is not directly involved. Please read also the General Brochure, which contains general information on medical research.

Once you have read this information and if you agree to participate, you will be asked to sign an informed consent form. The procedures related to the study will not commence before you have signed this form.

1. What is the purpose of this study?

The purpose of this study is to investigate whether patients who are being examined with Storz Professional Image Enhancement System (SPIES) experience less recurrence of cancer than patients treated with White Light Imaging (WLI) only. The study will, among others, be conducted in this hospital. Approximately 2,000 patients will participate in this study worldwide.

2. Which treatment is being investigated?

Diagnostics and treatment of bladder cancer with SPIES will be compared with WLI. WLI is the current standard for detecting and is used for removal of bladder cancer. SPIES is a new diagnostic technique that is developed to improve the imaging of cancer in the bladder. Special software has been designed to enhance the contrast between healthy tissue and tumor tissue. Therefore tumors will be better visible, and it is expected that because of this improved imaging, they will be easier to remove, because they are more detectable. With this study we will test whether patients effectively experience less recurrence of cancer after diagnostics with SPIES.

3. How will the research be performed?

The new SPIES technique will be used during the surgery (TURB), in the same manner as the current standard procedure (WLI). The SPIES technique will be additional to the standard procedure. This is a randomized study, which entails that patients will be randomly assigned to one of the two treatment arms. You have an equal chance of being assigned to either diagnostics and treatment with SPIES or diagnostics and treatment with WLI only. To perform the study as good as possible, only a limited number of people will be informed on which group you were assigned to. As a patient, you do not know to which group you were assigned. In the course of this study, a number of visits to the hospital are planned, which are in compliance with the standard procedure for this condition. First, your eligibility for this research will be determined, after that the preparation for surgery will take place. Subsequently the surgery will be performed, after which you will be invited to several follow up visits: after 3 months, 6 months, 12 months and then twice a year, for 3 years maximum after treatment. These follow up visits are part of the standard procedure after surgery for bladder cancer.

4. What is expected of you?

During this study, you can do everything you normally do. Female patients are encouraged to use contraceptives during the surgery and at least one month after. When appropriate, any anticoagulation treatment will be discontinued during surgery; this is the standard procedure for this surgery. We hope you will attend each follow up visit and we will help you with that by sending reminders.

5. Is there anything different from regular treatment?

Depending on which group you are assigned to, you will receive diagnostics and treatment with WLI only (standard procedure) or treatment with SPIES and WLI (new technique). Participation also entails several follow up visits for examination in the hospital. At these visits, recurrence of cancer is examined endoscopically. These visits are in compliance with standard follow up visits for bladder cancer.

6. Which side effects you expect?

In comparable studies no side effects were encountered. The only difference with the standard procedure is the (possible) additional use of SPIES, which may lead the surgery to last a few minutes longer.

7. What are the possible (dis-)advantages of participation in this research?

We hope that SPIES will improve the diagnostics and treatment of bladder cancer and will reduce the chance of cancer recurrence. Since every participant will at least receive the standard care, no disadvantages for you are associated with participating in this study. This research can provide us with important information for future use.

8. What will happen when you decide not to participate in this study?

You and only you decide if you want to take part in this study. Participation is completely voluntary. If you decide not to participate, there is nothing you need to do, you do not have to sign anything. You do not have to provide a reason for declining to participate. You will receive the standard procedure you would have received otherwise. If you do participate, you can always change your mind and stop with the study. Even when the study is already started. You do not have to provide the investigator with a reason.

9. What will happen when the study is finished?

There are no specific procedures that have to be followed after finishing of this study. You will find no disadvantage of finishing the study.

10. Are you insured when participating in this study?

Since there are no risks involved in participating in this study, the medical research ethics committee has granted exemption to the obligation of arranging a special damage insurance for the participants.

11. What will happen to your data?

During this research data concerning you will be gathered. These data remain confidential. Your data will be provided with a code and your name will be omitted. You will never find your name in any report on this study. Only the investigator and employees directly involved in the study will know which code is yours. A few other people are able to see your medical files. These people monitor the study for reliability. People who are able to see your medical files are those in the research team, representatives of the sponsor of the study and representatives of the agent controlling public health. We are required to store your data for 15 years and then destroy them. You will consent to that by participating in this study. If you do not want this, you can not participate.

12. Will there be compensation for participating?

No, for this study there is no compensation.

13. Which medical ethical committee has approved this study?

The medical committee of [XX] has approved of this study. More information concerning the approval can be found in the General Brochure.

Opmerking [IL1]: Insert the name of the medical ethical committee that has approved this trial.

14. Is there anything else you want to know?

You have got at least one week to consider participation in this trial. In case you have any questions, you can contact the principal investigator, you can find the contact details at the bottom of this page. If you would like an independent opinion on participation, please contact the independent expert: you can contact [name independent expert] at [telephone] or [email].

Opmerking [IL2]: Insert the name and contact information of the independent expert. Each center is responsible for their local independent expert, so details may differ between centers.

15. Appendices

You have received the following appendices with this information sheet:

- Appendix A: insurance information
- General Brochure medical research with human subjects

16. Contact details

Principal Investigator for this study: [name]

Telephone: []; email: []

Independent expert for this study: [name]

Opmerking [IL3]: Insert name and contact details from the local PI.

Telephone: []; email: []

Outpatient clinic Urology: [telephone and business hours]

In case of emergency, you can contact the nursing unit of Urology out-of-hours: telephone []

Opmerking [IL4]: Insert name and contact details from the independent expert.

Opmerking [IL5]: Insert when appropriate.

Opmerking [IL6]: Insert telephone number for emergencies.

Informed consent form participation in the ‘SPIES bladder cancer study’

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I have read the information sheet for patients. I was able to ask questions. My questions have been answered sufficiently. I had enough time to decide whether to participate or not.

I know participation is completely voluntarily. I know that I can decide to quit any moment. I do not have to provide a reason for that.

I give permission to inform my treating physician(s) about participation in this study (when applicable).

I know the research team, the representatives of the principal, and the Health Care Inspectorate are able to see my data.

I give permission to use my data for the objectives stated in the information sheet.

I give permission to store my data for 15 years after this study has ended.

I want to participate in this study.

Name patient:

Signature:

Date : __ / __ / __

I hereby declare that I have informed this patient fully about the above mentioned study.

When new information on the procedure being used arises that may influence this consent, I will notify him/her in a timely manner.

Name researcher (or its representative):

Signature:

Date: __ / __ / __

Additional information has been provided by (when applicable):

Name:

Function:

Signature:

Date: __ / __ / __
