

Information brochure for patients related to observational medical research involving IRE Nanoknife® for ablating prostate cancer

Title of the study

“IRE Registry”:

Registry of irreversible electroporation for the ablation of prostate cancer with use of Nanoknife® device. A multi-center, international registry to evaluate the treatment of prostate cancer in terms of recurrence, functional outcomes and safety.

Dear Sir,

You are invited to participate in this research study, because you have been diagnosed with prostate cancer and will be receiving treatment with use of the Nanoknife®. During your visit(s) at this hospital, the information collected about you by the medical staff during standard care will be used for this research project that will evaluate the treatment.

You participation is voluntary

Your participation is entirely voluntary, so it is up to you to decide whether or not to take part in this study. Before you decide, it is important for you to understand why the research is being done, what will happen to you during the registry and the benefits, risks and discomforts.

Please take time to read the following information carefully and to discuss it with your family, friends and physician before you decide.

If you wish to participate, you will be asked to sign this form. If you decide to take part, you are still free to withdraw at any time and without giving any reasons for your decision.

If you do not wish to participate, you do not have to provide any reason for your decision nor will you lose the benefit of any medical care to which you are entitled or are presently receiving.

Who is conducting this registry?

The Principal Investigator [xx] is conducting the registry in this center. This registry is initiated by the Clinical Research Office of the Endourological Society (CROES) and will be conducted in several centers worldwide.

Opmerking [IL1]: Insert the name of the local PI here

1. What is the purpose of the registry?

This registry is set up to assess the recurrence of prostate cancer in patients who were treated with Irreversible Electroporation (IRE) with use of the Nanoknife®, determine the baseline characteristics of the patients and to collect information on possible differences concerning side effects and outcome of the treatment between centers.

2. Who can participate in the registry?

Participants diagnosed with prostate cancer and scheduled for treatment with IRE Nanoknife®.

3. What does the registry involve?

This registry will take place at this center. You will receive the IRE treatment for prostate cancer. The investigator is collecting data that already has been collected in the course of normal care. This information could include your medical condition, medications, test results and other chart information. Also treatment data and side effects and outcome data are collected during 5 years after treatment. The information collected for this study is coded and will not be reducible to you.

4. What are my responsibilities?

This is an observational study and does not require your active participation, other than the accept release of your information for research purposes.

5. What are the possible harms and side effects of participating?

There are no risks associated with this registry. The information the participants reveal will not affect their health care.

6. What are the benefits of participating in this registry?

There may or may not be direct benefits to you from taking part in this registry. We hope that the information collected from this registry can be used in the future to benefit other men with prostate cancer.

7. Is there anything different from regular IRE treatment?

No, all patients will receive the same IRE treatment as they would have received should they not participate.

8. What happens if something goes wrong?

Signing this consent form in no way limits your legal rights against the investigators, or anyone else.

9. Will there be compensation?

Since participating in this registry requires nothing more than gathering data that already has been collected in the course of standard care, patients will be not paid for their participation in this registry.

10. Who do I contact if I have questions about the study during my participation?

If you have any questions or desire further information, you can contact the local Principal Investigator: at .

Opmerking [IL2]: Insert name of local PI

Opmerking [IL3]: Insert telephone number of PI

Informed Consent Form participation in the “IRE Registry”

I have read the information brochure 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 understand that all of the information collected will be kept confidential and that the results will only be used for scientific objectives.

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

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 : __ / __ / __

Principal Investigator (or designate)

Signature:

Date : __ / __ / __