Comparison of Endovascular and Open Repair of Juxta- and Pararenal Abdominal Aortic Aneurysm on Short- and Long-term Clinical Outcomes

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INFORMATION LETTER FOR PATIENTS

We invite you to participate in our research, with a subject of comparison of two treatment modalities, open-surgical and endovascular of complex abdominal aortic aneurysms (AAA). A comparison of these two treatments will be made in terms of short-term and long-term outcomes with the aim of accurately identifying the factors that affect early and late survival. This will have undoubted practical and clinical significance, as it will allow better patient choice for one of these two treatment modalities. Before deciding whether to participate, it is important to understand why this comparison and monitoring of the effects of the two modalities of treating complex AAAs is done and what it implies.

Please read the following information carefully and, if you wish, discuss this with the treating physician, if you feel it is necessary. If something is unclear or if you want more information we will be happy to answer your questions. You have enough time to decide whether you accept to participate.

Thank you for taking the time to read this information.

- What is the goal of this additional monitoring of the therapy effect? (1)

The disease you have been suffering from (abdominal aortic aneurysm - AAA) is a very insidious disease whose most common complication (rupture, i.e. rupture) usually ends fatally. This is especially the case in patients who have a more complicated form of AAA when it affects the arteries that feed kidneys. So far, there is no consensus on which of these two modalities of treatment of complex AAA should be used. Both treatments have their drawbacks and benefits, and the aim of this research will be to compare them and identify the factors that affect poor survival in both groups, so that they can be corrected in order to reduce the possibility of fatal short- and long-term outcomes. Consequently, this will enable better selection of patients when choosing treatment and improve outcomes by better controlling factors that affect poorer survival.

- Why were you chosen? (2)

The degree of progression of aneurysmal disease in your case is such that it requires surgical treatment according to recent guidelines and criteria. As you have already agreed to surgical treatment, you will be included in our multicenter study (including leading European centers dealing with the treatment of complex AAA). Your hospital data will be entered into a single database and you will be regularly monitored according to a pre-defined protocol. It is important to understand that if you allow us to collect your data acquired during the hospital stay and during the follow-up for research purposes, we will compare these two treatment modalities and your data would be anonymzed.

- Are you required to participate? (3)

Your decision to help monitor the effects of therapy does not in any way affect your treatment, nor are you obligated to participate in it, but we are obligated to inform you accurately about all this.

- What will happen if you decide to participate in monitoring the effects of therapy? (4)

If you accept to participate in the explained study, you have no additional obligations because these data are routinely taken during the patient hospital stay, as well as data that are entered into operating systems when monitoring patients.

- What are the possible benefits and problems of participation? (5)

If we want to recognize the benefits of participation, they are certainly oriented towards more accurate assessment of the effects of two treatment modalities for complex AAA, which will be of great benefit to future patients who have the same condition, while your treatment outcome will have neither positive nor negative impact.

- Will your participation and all data related to it be kept confidential? (6)

All the information we acquire about you and your disease represents the medical secrecy, for the storage of which both your doctor and the entire medical staff are responsible.

- What is the purpose of monitoring and what will the results be used for? (7)

These data can only be used as aggregate data for a large number of patients participating in this study. Based on a larger number of results of such monitoring, we can provide a more precise and better therapeutic approach in all other cases for the same disease than it has been so far.

- Who organizes and finances this, additional monitoring of the effects of therapy? (8)

Additional funding for this research is not provided and it is done exclusively for scientific purposes.

- What happens if you are worried, if you have any questions about monitoring the effects of therapy, and / or if there is an emergency? (9)

You will be able to contact your doctor who is also responsible for the research, to talk about what worries you or to ask for help: _____ (NAME THE RESPONSIBLE PARTIES).

If you agree to participate in this study, we will provide you with a copy of this information sheet and a signed informed consent form to keep, as the procedure provides that you also have this type of information.

_____ (NAME THE CENTER)

CONSENT TO PARTICIPATE IN THE RESEARCH STUDY

Name of participant _____

Number of respondents: _____

By signing this consent, I certify that:

o I received oral and written information on monitoring the effects of therapy and I read and understood the information received.

o I had enough time to consider my participation as well as the opportunity to ask questions and I received satisfactory answers to all my questions.

o I understand that my participation is voluntary and that I am free to terminate my participation in monitoring the effects of therapy at any time, without having to state a reason for it, and that it will in no way affect my future treatment.

o I understand that only medical professionals, clinical staff of the _____ (NAME THE CENTER), can have access to my health file to ensure that the effects of therapy are monitored correctly and that data is properly recorded. All personal data will be considered STRICTLY CONFIDENTIAL. I understand that the data collected during my participation in this monitoring of the effects of therapy are entered into a database and analyzed, and will be used exclusively for scientific purposes.

o I understand that the data collected during my participation in this research is entered into a database and analyzed, and will be used exclusively for scientific purposes.

o I will receive a signed and dated copy of this notice.

o I agree to participate in this research.

Doctor: _____

Date: Signature: _____

Name (printed): _____

Patient: _____

Date: Signature: _____

Name (printed): _____