Informed Consent Form Cover Page Official Study Title: : Efficacy of Eco-guided Percutaneous Transperineal Ablation with Neodymium Laser in Patients with Low-Intermediate Risk Prostate Cancer: Non-Pharmacological Interventional Study

R.S 68:19
Approval date: 06/12/2019

INFORMATION SHEET

Dear Sir,

in this University Polyclinic a non-profit research is planned entitled " Efficacy of Eco-guided Percutaneous Transperineal Ablation with Neodymium Laser in Patients with Low-Intermediate Risk Prostate Cancer: Non-Pharmacological Interventional Study ". To carry out this research we need the collaboration and availability of people who, like you, present the appropriate scientific requirements for the evaluation that will be performed during and after the study. Before you make the decision to accept or refuse to participate, please read these pages carefully, taking all the time you need, and ask us for clarification if you do not understand or need further clarification. Furthermore, if you wish, before deciding, you can ask an opinion of your doctor or whoever you think is appropriate.

ALTERNATIVE TREATMENTS

Currently the therapeutic protocol accepted according to the AIO Guidelines 2018 for prostate cancer in patients considered to be at intermediate risk - PGG 2 or 3 consists of radical prostatectomy or external radiotherapy, methods that positively impact both as overall survival and as cancer-specific.

OBJECTIVE OF THE STUDY

With this we intend to evaluate the short-term safety and efficacy of percutaneous ablative treatment with neodymium laser of prostate cancer, ie the complete profile of safety and tolerability in acute and in follow-up, in patients with prostate cancer intermediate risk and low risk that reject the active surveillance protocol and then surgery or radiotherapy, using the multiparametric prostate magnetic resonance as a diagnostic tool in the follow-up.

WHAT IS YOUR PARTICIPATION IN THE STUDIO

If you decide to participate in the Study, you will be evaluated by a multidisciplinary commission according to specific inclusion criteria. If it is suitable, it will be included in the Study. The percutaneous treatment is preceded by a local anesthetic of the perineal region, under ultrasound guidance. At the discretion of the medical team, sedation can be carried out with the assistance of a specialist in Anesthesiology and Resuscitation.

After identifying the lesion using a trans-rectal ultrasound with the fusion technique of the echo-MR image, and following the administration of local anesthesia, 1 or 2 guide needles will be inserted (from 21G), in correspondence with the diagnosed neoplastic lesion . In each needle a 300 micron optical fiber will be inserted with a coaxial technique. Following the evaluation of the correct positioning of the fibers, an energy of 1800 J per fiber will be delivered, with a power of 2-5 Watts for a total duration of approximately 15 minutes. Overall, the procedure lasts about 30 minutes on average.

Your participation does not entail any additional costs.

INVESTIGATIONS TO WHICH IT WILL BE SUBMITTED DURING THE STUDY

The study foresees the carrying out of the diagnostic investigations described below.

Specialist examination with serum PSA and multi-parametric MR prostate (after administration of paramagnetic intravenous contrast agent) at 3-6-12 months.

Random prostatic biopsy and prostatic fusion biopsy (as usual in clinical practice) at 6 and 12 months.

Subsequently a specialist visit with PSA tot and free every 6 months for the first 3 years then

annually. Repetition of multiparametric prostate MRI and biopsies every 12 months for the first 3 years then every 18 months up to 5 years.

DEVICE IN STUDIO / EXPERIMENTAL PROCEDURE

Focal percutaneous ablative treatment with laser at the diode of the focal prostate tumor, with evaluation of the effectiveness after treatment and in the short-term follow-up, by multi-parametric MR prostate.

WHAT ARE THE RISKS AND THE SIDE EFFECTS ARISING FROM THE PARTICIPATION IN THE STUDIO Clinical trials (Lindner et al, and Oto et al.) Have demonstrated the short-term efficacy of focal laser ablation provided in the study in low-risk patients.

No complications have been reported peri-operatively. In the post-operative period, new onset erectile dysfunctions and no significant changes in the main scales of evaluation of male function have been documented: SHIM (Sexual Health Inventory for Men), IIEF (International Index of Erectile Function), AUASS (American Urological Association Symptom Score) or IPSS (International Prostate Symptom Score). All patients were able to urinate spontaneously within 3 days after laser ablation. Post-operative morbidities include perineal discomfort (25%), mild hematuria (17%), hematospermia (8%) and fatigue (8%), all conditions that resolve spontaneously. Perineal abrasion and transient glans paraesthesia have been reported as rare adverse events. Few patients are still undergoing laser ablation follow-up studies. Bioptic controls of the ablated region performed 3-6 months after FLA used for therapeutic purposes on selected lesions showed residual disease in 4% of treated patients (Lepor et al). In the case of residual / recurrent disease, subsequent treatments, both of focal laser ablation, and of radical therapy, such as surgery and radiotherapy, can be carried out at any time after the focal laser ablation procedure. Therefore the focal laser ablation (FLA) does not preclude a subsequent optimal therapeutic treatment.

INSURANCE POLICY

Compensation for any damage you may suffer as a result of your participation in the Study is covered by the company insurance policy covering the common clinical practice. A copy of the insurance policy is available at the clinical center for a possible consultation. WHAT ARE THE BENEFITS THAT YOU MAY RECEIVE BY ATTENDING THE STUDY

The following direct and / or indirect benefits (for future patients) can be expected from participation in this study: destruction by laser ablation of the prostatic neoplastic lesion diagnosed by you with a minimally invasive method.

WHAT HAPPENS IF YOU DECIDE NOT TO ATTEND THE STUDY

You are free not to participate in the Study. In any case you will receive all the therapies provided for your condition without any penalty, and the doctors will continue to follow you anyway with due care, even if there are no other therapies available.

INTERRUPTION OF THE STUDY

Your participation in the study is completely voluntary and you can withdraw at any time and for any reason without having to provide explanations, possibly communicating it to the doctor who follows you for this study.

CONFIDENTIALITY OF PERSONAL DATA

We inform you that your personal data will be collected and stored electronically and will be used exclusively for scientific research purposes.

You have the right to know what information will be stored and to update or change incorrect data. Access to these data will be protected by the Investigator (the doctor who follows you during the Study). Regulatory authorities (Ministry of Health), medical staff, monitoring and verification of correct procedures (Independent Ethics Committee) will be able to inspect the archive without the possibility of tracing back to your personal identity.

The results of the study in which it participates may be published but your identity will always remain secret, in full compliance with the legislation in force in Italy on the protection of personal data D.Lgs.196 dated 30.06.2003 / GDPR679 / 2016.

INFORMATION ABOUT THE RESULTS OF THE STUDY

If you request it at the end of the study, the results of the study in general and in particular those that concern you if they are available will be communicated to you.

FURTHER INFORMATION

The proposed Study Protocol was drafted in accordance with the "Rules of Good Clinical Practice" of the European Union and the current revision of the Helsinki Declaration.

The Study and this informed Consent have been approved by the Independent Ethics Committee operating at this Hospital. The Committee is an independent body made up of experts in various disciplines, working to protect and guarantee patients involved in clinical trials. To the same Committee, you can report any fact it deems appropriate to highlight, which regulates it, relative to the Study.

DECLARATION OF CONSENT

I, the undersigned: _____

born in _____the _____, residing in _____

on _____,

DECLARE

• to have received comprehensive explanations regarding my participation in the Study "Efficacy of the Trans-perineal Eco-guided Percutaneous Ablation of Magnetic Resonance Fusion with Neodymium Laser in patients with Unifocal Prostatic Neoplasia: Multidisciplinary Pilot Interventional Study". as reported in the attached information sheet, a copy of which was delivered to me sufficiently in advance;

• to have been able to discuss these explanations; to have been able to ask all the questions that I deemed necessary and to have received satisfactory answers, to therefore be aware of all the possible risks and benefits that may derive from my participation in the Study;

• to be aware that at any time and for any reason I will be able to withdraw from the Study, and in any case be treated with the ordinary therapies for the illness of which I suffer, without the obligation to motivate the decision, unless it derives from the appearance of disorders or unwanted effects, in the event I undertake to contact the doctor who follows me during the study promptly;

• that my participation is free, not influenced by promises of money or other benefits, nor by obligations of gratitude or friendship and / or kinship towards the doctor who proposes the study;

• to have been informed of my right to have free access to the documentation relating to the Study (insurance, clinical-scientific, therapeutic), and to the evaluation expressed by the Independent Ethics Committee;

• to authorize the use and disclosure, anonymously, for scientific and administrative purposes only and in compliance with the regulations in force on the protection of confidentiality, of the results of the Study, including the clinical data concerning me, in full compliance with current legislation in

Italy on the protection of personal data (Legislative Decree 196/2003 / GDPR 679/2016);

- to have been informed that the trial is covered by the Insurance Policy
- to freely accept, therefore, to participate in the Study, having fully understood the meaning of my participation having understood the risks and benefits involved.

Date Signature of the patient

_____ _____

Date The investigating doctor

_____ _____

The investigator doctor
(in block letters)

Information and consent for the processing of personal data

Data controllers and related purposes

The Clinical UOC Center of RADIOLOGY AND UOC of UROLOGY of the PTV Foundation Policlinico Tor Vergata, Promoter of the Firm, according to the responsibilities foreseen by the norms of the good clinical practice (D.Lgs. 211/2003), will treat your personal data, in particular those on health, exclusively to the extent that they are indispensable in relation to the objective of the study.

To this end, the data indicated will be collected at the Testing Center in full compliance with the legislation in force in Italy on the protection of personal data (Legislative Decree 196/2003).

The processing of personal data is essential for the conduct of the study: the refusal to grant them will not allow you to participate.

Nature of the data

The doctor who will follow you in the study will identify you with a code: the data relating to you collected during the study, with the exception of your name, will be recorded, processed and stored together with this code, your date of birth and gender. The Study Promoter Experimentation Center will process your personal data, both generic (name, surname, date of birth, etc.) and your health status, anonymously and exclusively according to the implementation of the research program . Only the doctor and his authorized collaborators can link this code to your name.

Processing methods

The data, processed using electronic or electronic means, will be disseminated only in strictly anonymous form, for example through scientific publications, statistics and scientific conferences. Your participation in the study implies that, in accordance with current legislation, the staff of the Ethics Committee and the Italian health authorities will be able to know the data concerning you, also contained in your original clinical documentation, in such a way as to guarantee the confidentiality of your identity.

Consent

By signing this form I consent to the processing of my personal data for research purposes within the limits and in the manner indicated in the information provided to me by this document.

Name and surname of the person concerned (in block capitals) _____

Signature of the interested party _____

Date _____

TO BE COMPLETED BY THE DOCTOR WHO OBTAINED CONSENT

I confirm that I have provided the patient with exhaustive explanations about the nature, purpose and duration of the topic study and that he gave him a copy of the information sheet and a dated and signed copy of the consent form.

I also confirm that I have provided the patient with information relating to the processing of personal data and that I have received explicit written consent to the processing.

Name of the Doctor who obtained consent:

Name and Surname: _____

Date (day/month:year): |_|_|/|_|_|/|_|_|_|_| Signature: _____