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S.C. UROLOGIA
Presidio Molinette
Direttore Prof. Paolo Gontero
tel. 011.6335416 - fax 011.6336471

Informed Consent

Project title:

Surgical and oncological outcomes of the laparoscopic assisted radical inguinal lymphoadenectomy for cN1/N2 penile cancer: a prospective comparative study between open ad laparoscopic approach

Local Ethics Committee Approval n° 00025/2020 of date April 4, 2020

Date: March 31, 2020 version 1

Principal Investigator: **dr Marco Falcone**

Physician Investigator:
……

I, the undersigned ……..... born in ……on……,address……

……Phone number……

DECLARE

- That I have penile cancer with an indication for bilateral inguinal lymphadenectomy according to the 2019 EAU guidelines: clinical stage N1/N2 (lymph nodes palpable mono/bilaterally, but not fixed) or high-risk tumor (>T1G2).

- That I have been informed of all available treatment options.

- To voluntarily participate in the present study, having the following aims:

- to prospectively compare the oncologic and functional outcomes of radical inguinal lymphadenectomy of the penis performed with open versus video-laparoscopic technique

- compare peri/postoperative complications of open VS video-laparoscopic lymphadenectomy, surgical time of procedures, number of lymph nodes excised, number of lymph nodes found to be metastatic, and hospital stay
- compare survival analysis with assessment of lymph node recurrence, cancer-specific survival (CSS), and overall survival (OS)

- That I have received full explanations from the Investigator Physician regarding participation in the research, particularly the purposes and procedures

- That I have had sufficient time to be able to carefully read, understand, and possibly have explained to me what is contained in the enclosed information sheet, which I have signed for acknowledgement, and which confirms what has been explained to me verbally, in particular that the trial will be conducted in accordance with international ethical codes

- That I have had the opportunity to ask questions and have received satisfactory answers about the entire trial and in particular about the possible diagnostic and therapeutic alternatives

- That I have been informed of the possible risks or discomforts reasonably foreseeable

- to consent/not to consent for the responsible physician to inform my family physician

- to be aware that participation is voluntary, with the assurance that refusal to

participate will not affect receiving the most appropriate treatment

- that I may retire from the trial that has already begun at any time, without adverse consequences in receiving the most adequate treatment and without any obligation on my part to give reasons for the decision, unless it arises from the occurrence of undesirable and/or unforeseen disorders or effects, in which case I undertake as of now to notify the investigating physician promptly of their nature and extent

- That the medical records will remain strictly confidential and the data will be used with the purposes indicated in the study (according to Legislative Decree 196/2003)

- that I will be informed of any new data that may affect the risks or benefits, or of changes in protocol that may affect them

- that it is my right to have access to the documentation concerning me and to the evaluation expressed by the Ethics Committee to which I may address myself if I deem it appropriate

Privacy and use of clinical information

To carry out the study, it will be necessary to use certain information in your medical records. Your consent will authorize us to use this information, in accordance with the right of privacy protection (d.lgs. 196/2003 and s.m.i. as per the Guidelines of the Guarantor for the processing of personal data in the context of clinical trials of medicines (G.U. 190 of 14/08/2008) and as per any other prescription/authorization of the same Guarantor). All information collected will be collected anonymously, within a database, for statistical analysis.

I am aware that for any problems or for any further information I can contact the Experimental Physician of UROLOGY (phone 0116335707).

Therefore, I confirm that I have had comprehensive answers to all my questions and, having noted the situation outlined.

I AGREE

FREELY, SPONTANEOUSLY AND IN FULL CONSCIOUSNESS TO THE EXPERIMENTATION PROPOSED TO ME.

Date …….. Patient’s signature …….

Physician's signature…….

OR

I DO NOT AGREE

FREELY, SPONTANEOUSLY AND IN FULL CONSCIOUSNESS TO THE EXPERIMENTATION PROPOSED TO ME.

Date …….. Patient’s signature …….

Physician's signature …….