Prometheus: Prophylactic Mesh After OLtx for Hernia Reduction Study. A Multicenter Prospective, Consecutive Case Series Study, on the Use of a Bio-absorbable Mesh for Prevention of Incisional Hernia, in High Risk Patients, After Orthotopic Liver Transplantation.

Informed Consent (English Translation)

25/09/2024

Dear Sir/Madam,

The purpose of this informed consent is to invite you to participate in a research project **"STUDY OBSERVATIONAL PROMETHEUS", whose aim is to collect data regarding the population of patients undergoing liver transplantation from a deceased donor.**

You may decide—based on the information you have received and with complete freedom—whether to authorize the collection and processing of your sensitive personal data (e.g., your health status).

Study objective
The objective of this observational epidemiological study is to acquire and analyze data related to the use of biosynthetic prostheses in routine surgical clinical practice in liver transplantation from deceased donors, in order to deepen knowledge regarding safety and effectiveness in preventing complications and, in particular, incisional hernias (laparoceles) at the closure site. The study also aims to investigate the costs associated with this type of procedure, both in terms of healthcare resources used and expenses incurred by the patient and their family members.

What participation in the study involves
This study does not aim to modify therapy, administer different drugs from those currently in use, or subject you to therapeutic or diagnostic procedures other than those planned for you as part of routine clinical practice. After the surgical procedure scheduled for you as part of routine clinical practice, you are at high risk of laparoceles (a hernia that forms on a scar after surgery). If you decide to participate in the Study, you will undergo data collection, which will be carried out **exclusively during routine follow-ups (according to the practice of the participating centers) using dedicated data collection forms. These forms will collect information regarding your clinical history, the incidence of previous infection episodes, and the incidence of clinical events.**

What are the risks resulting from participation in the study?
The Study does not include procedures different from usual clinical practice for patients at high risk of laparoceles; therefore, it involves no additional risks. Your participation allows us simply to collect and analyze information and disseminate it to the scientific community in full compliance with the applicable regulations on the processing of personal data (GDPR 679/2016; Italian Legislative Decree No. 196/2003 as amended by Legislative Decree No. 101/2018).

What happens if you decide not to participate in the study
You are free to not participate in the Study. In any case, you will receive all tests and therapies planned for your condition, without any penalty, and the physicians will continue to care for you with the necessary level of attention.

Study interruption
Your participation is completely voluntary and you may withdraw at any time and for any reason, if possible informing the physician who is following you for this Study.

Consent statement

I, the undersigned:
declare that I have received from **Dr. _____**
full and sufficient explanations regarding my participation in the **"PROMETHEUS – Observational, multicenter, prospective, consecutive study on the use of a bioabsorbable mesh for the prevention of incisional hernia after orthotopic liver transplantation in high-risk patients"**
according to what is reported in the attached information sheet, a copy of which was provided to me with sufficient advance notice;

- that I was able to discuss these explanations; that I was able to ask all questions I considered necessary and that I received satisfactory answers regarding my participation in the Study;
- that I am aware that at any time and for any reason I may withdraw from the Study and will still receive treatment with the usual therapies for my disease, without the obligation to provide reasons;
- that my participation is free, not influenced by promises of money or other benefits, nor by obligations of gratitude or friendship and/or family ties toward the physician proposing the Study;
- that I have been informed of my right to freely access documentation concerning me related to the Study and the assessment expressed by the Independent Ethics Committee;
- that I hereby authorize, from now on, the use and disclosure, in anonymous form, for scientific and administrative purposes only, and in compliance with applicable rules on confidentiality, of the results of the Study, including the clinical data concerning me, in full compliance with the current Italian regulations on the protection of personal data (GDPR 679/2016; Italian Legislative Decree No. 196/2003 as amended by Legislative Decree No. 101/2018);
- that I therefore freely accept to participate in the Study, having fully understood the meaning of my participation.

Date _____ **Patient signature _____**

Date _____ **Investigator signature _____**

Information and consent statement for the processing of personal data

Data controllers and purposes
The **UOC Surgery, Hepatobiliary Surgery and Transplant Unit of the **Fondazione PTV "Policlinico Tor Vergata"** — sponsor of the observational Study described to you — in accordance with the responsibilities provided for by the rules of good clinical practice, will**

process your personal data, in particular health data, and only to the extent indispensable in relation to the study objective, fully in compliance with the applicable regulations on personal data protection (GDPR 679/2016; Italian Legislative Decree No. 196/2003 as amended by Legislative Decree No. 101/2018). To this end, the specified data will be collected by the Study Center and processed at the same.

The Data Protection Officer for the healthcare company is **Avv. I. Lucati
The clinical center can be contacted at the following email address: **DPO@ptvonline.it****

Processing of personal data relating to your health, age, and sex is necessary to carry out the study: refusal to provide them will not allow you to participate.

Nature of the data
The physician who will follow you in the study will identify you using a code. The data concerning you collected during the study—except your name—will be recorded, processed, and stored together with that code, along with your health status, date of birth, and sex. Only the physician and legally authorized parties will be able to link this code to your identity.

Methods of processing
The data, processed using tools including electronic ones, will be disclosed only in strictly anonymous form, for example through scientific publications, statistics, and scientific conferences.

Information and consent statement for the processing of personal data (consent section)

Data controllers and purposes
The **UOC Surgery, Hepatobiliary Surgery and Transplant Unit of the **Fondazione PTV "Policlinico Tor Vergata"** — sponsor of the observational Study described to you — in accordance with the responsibilities provided for by the rules of good clinical practice, will process your personal data, in particular health data, and only to the extent indispensable in relation to the study objective, fully in compliance with the applicable regulations on personal data protection (GDPR 679/2016; Italian Legislative Decree No. 196/2003 as amended by Legislative Decree No. 101/2018). To this end, the specified data will be collected by the Study Center and processed at the same.**

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Methods of processing
The data, processed using tools including electronic ones, will be disclosed only in strictly anonymous form, for example through scientific publications, statistics, and scientific conferences.

Exercise of rights
You may exercise your rights in accordance with the applicable regulations on the protection of personal and sensitive data (GDPR 679/2016; Italian Legislative Decree No. 196/2003 as amended by Legislative Decree No. 101/2018), for example by accessing your personal data, supplementing them, updating them, correcting them, objecting to their processing for legitimate reasons, etc., by contacting directly the physician who is following you, **Dr. A. Anselmo, reachable at phone number **0620908294**. You may also contact the Data Protection Officer for the healthcare company; the clinical center can be reached at: **DPO@ptvonline.it****

You also have the right to lodge a complaint with the Italian Data Protection Authority (www.garanteprivacy.it**; email: **garante@gpdp.it**; +39 06.696771).**

You may interrupt your participation in the study at any time and without providing any justification. No additional data concerning you will be collected; however, any data already collected will continue to be used—without alteration—to determine the study results, unless you request their deletion.

Consent
By signing this form, I consent to the processing of my personal data for the research purposes within the limits and using the methods indicated in the information provided to me.
