Informed consent form (ICF)

ROLE OF O2 AVAILABILITY IN ANASTOMOTIC LEAKAGE IN LAPAROSCOPIC COLORECTAL SURGERY FOR CANCER

version I 7th June 2020
Approved by local Ethics Committee on 23rd July 2020
(Protocol n. 00154/2020)

SANT'EUGENIO HOSPITAL
INFORMED CONSENT

OBSERVATIONAL STUDY

ROLE OF O2 AVAILABILITY IN ANASTOMOTIC LEAKAGE IN LAPAROSCOPIC COLORECTAL SURGERY FOR CANCER

Dear Patient,

The purpose of this informed consent is to propose your participation in a non-profit research, an observational study entitled: ROLE OF O2 AVAILABILITY IN ANASTOMOTIC LEAKAGE IN LAPAROSCOPIC COLORECTAL SURGERY FOR CANCER. This study will exclusively collect data on patients undergoing elective laparoscopic colorectal surgery.

You will be able to decide, based on the information received and in complete freedom, whether to authorize the collection and processing of your sensitive personal data (e.g., your health status).

Study Objective

The prospective, observational objective of the study is to evaluate the effects of DO2I on the incidence of anastomotic leakage in patients undergoing laparoscopic resective surgery for colorectal cancer.

What does participation in the study entail?

The study does not intend to modify your therapy, administer medications other than those currently in use, or subject you to therapeutic or diagnostic procedures other than those prescribed for you as part of standard clinical practice for the treatment of your condition. If you decide to participate in the study, you will be subjected to data collection that will be carried out exclusively

perioperatively, using dedicated data collection forms. Information regarding your medical history will be collected.

What are the risks of participating in the study?

The study does not involve procedures other than standard clinical practice, therefore it does not present any additional risks. Your participation simply allows us to collect and analyze information and disclose it to the scientific community in full compliance with current legislation on the processing of personal data (Legislative Decree 196/2003 and GDPR 679/2016).

What happens if you decide not to participate in the study?

You are free not to participate in the study. In any case, you will receive all the tests and treatments planned for your condition, without any penalty, and the doctors will continue to monitor you with the necessary medical care.

Interruption of the study

Your participation in the study is completely voluntary, and you may withdraw at any time and for any reason, preferably by notifying the physician who is following you for this study.

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, who work to protect and safeguard the patients involved in clinical studies.

Consent Statement

I, the undersigned:

declare that I have received from Dr. _____

extensive explanations regarding my participation in the "Observation Study entitled:

Role of O2 Availability in Anastomotic Leakage in Laparoscopic Colorectal Cancer Surgery" as reported in the attached information sheet, a copy of which was delivered to me sufficiently in advance;

• that I have been able to discuss these explanations; that I have been able to ask all the questions I deemed necessary and have 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 still be treated with the standard therapies for my disease, without the obligation to provide a reason for my decision;

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

• that I have been informed of my right to free access to my documentation related to the Study and to the assessment made by the Independent Ethics Committee;

• I hereby authorize the use and disclosure, anonymously, for scientific and administrative purposes only, in compliance with the applicable privacy laws, of the results of the Study, including my clinical data, in full compliance with the current Italian legislation on the protection of personal data (Legislative Decree 196/2003 and GDPR 679/2016);

• I therefore freely agree to participate in the Study, having fully understood the significance of my participation.

Date Signature of patient

_____ _____

Date Signature of investigator

_____ _____

Information and consent to the processing of personal data

Data controllers and related purposes

The Clinical Center, ANESTHESIA AND INTENSIVE CARE Unit of Sant'Eugenio Hospital, sponsor of the observational study described to you, in accordance with the responsibilities established by the rules of good clinical practice, will process your personal data, particularly health-related data, only to the extent necessary for the study's objective, in full compliance with current legislation on the protection of personal data (Legislative Decree 196/2003 and GDPR 679/2016).

To this end, the data indicated will be collected by the Trial Center and processed there. We inform you that the above-mentioned Data Controller, pursuant to Article 37 of GDPR 2016/679, has identified and appointed the Data Protection Officer (also "Data Protection Officer" or "DPO"):

Dr. Massimo GALLETTI

Legal Basis for Processing

The informed consent, freely given by you, constitutes the legal basis for the processing of your data for the purposes described in the information sheet. Without your signed consent, we will not be able to use your data to conduct and analyze the Study.

The processing of personal data relating to your health, age, and gender is essential for the conduct of the study: refusal to provide such data will prevent you from participating.

Special Categories of Personal Data

Pursuant to Articles 26 and 27 of Legislative Decree 196/2003 and Articles 9 and 10 of EU Regulation No. 2016/679, you may provide the data controller with data that qualifies as "special categories of personal data," meaning data revealing "ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, as well as genetic data, biometric data intended to uniquely identify a natural person, data concerning health or data concerning a natural person's sex

life or sexual orientation." These categories of data may be processed only with your prior free and explicit consent, expressed in writing at the bottom of this policy.

Nature of the data

The doctor who will be following you in the study will identify you with a code: the data about you collected during the study, with the exception of your name, will be recorded, processed, and stored together with this code, your health status, date of birth, and gender. Only the doctor and persons authorized by law will be able to link this code to your name.

Method of processing

The data, processed using electronic means, will be disclosed only in strictly anonymous form, for example through scientific publications, statistics, and scientific conferences.

Exercise of Rights

You may exercise the rights set forth in Article 7 of the Privacy Code (Legislative Decree 196/2003 as well as those set forth in Articles 15 to 22 of GDPR 679/2016), such as accessing, supplementing, updating, or correcting your personal data, objecting to its processing for legitimate reasons, etc., by contacting your doctor, Dr. Massimo GALLETTI, directly. You can reach him at 0651002979. You also have the right to lodge a formal complaint with the Data Protection Authority in the event of a violation of your privacy rights.

Right to information

You have the right to obtain information about your personal data, how it will be collected, processed, or, if necessary, transferred to third parties. You may discontinue your participation in the study at any time and without providing any justification. No further data about you will be

collected, except for the use of any data already collected to determine, without altering, the research results, unless you request that it be deleted.

Consent

I, the undersigned, in light of the information received, I consent to the processing of my personal data, including those considered special categories of data.

I consent to the communication of my personal data to public bodies and private companies for the purposes indicated in the information.

Name and Surname of the interested party (in capital letters) _____

Signature of the interested party _____

Date _____

ATTENTION: TO BE COMPLETED BY THE DOCTOR OF THE STUDY WHO OBTAINED THE CONSENT

I confirm that I have provided the patient with comprehensive explanations regarding the nature, purpose, and duration of the study in question and that I have provided him/her with a copy of the information sheet and a dated and signed copy of theconsent form.

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

Name of the physician who provided and withdrew the consent form:

Legible first and last name (or stamp):

_____

Date (dd/mm/yyyy): |_|_|/|_|_|/|_|_|_|

Signature:

_____