COLLATERAL STUDY

16/04/2024

ID: 6646

INFORMED CONSENT FORM

Transit Time Flow measurement in coronary surgery. The mutual influence of collateral flow between different coronary territories on parameter metrics: the COLLATERAL Study.

Dear Patient,

At the Fondazione Policlinico A. Gemelli IRCCS we'are planning a medical-scientific research entitled

"Transit Time Flow in Coronary Surgery. The mutual influence of collateral flow in different coronary territories. COLLATERAL study. "

This research is monocentric.

To carry out this research we need the cooperation and availability of people who, like you, meet the scientific requirements for the evaluation that will be carried out. However, before you accept or refuse to participate, please read this document carefully, taking all the necessary time and ask us if you need further clarification.

In addition, if you wish, you can also ask your family members or your doctor for an opinion before deciding.

AIM OF THE STUDY

The objective of this study is to verify the correct functioning of newly packaged bypass through the measurement of blood flow.

In details, we intend to obtain data related to the measurements of the flows inside the ducts used for the packaging of bypass and the patency of anastomoses. This constitutes a quality control to verify the correct execution of the bypass at the end of the surgery.

This quality check is routinely carried out, but in this study we will record such data to increase the knowledge on bypass flows.

YOUR PARTICIPATION IN THE STUDY

The study does not provide additional acts in comparison with normal clinical practice:

- only the collection of intra-operative data is envisaged (recording of coronary flows following the appropriate protocol).

The study will last 18 months and 135 patients will be enrolled.

RISKS

The participation to the study does not involve any investigation or treatment other than that provided in normal clinical practice and therefore there will be no additional risks for the patients enrolled in the study.

BENEFITS

There will be no benefits directly to you, but your participation will allow us to acquire additional informations about your disease.

REFUSE TO PARTICIPATE

You are free to refuse the inclusion to the study. In this case, you will however receive all the standard therapies provided for your pathology, without any penalty, and the doctors will continue to follow you with due care.

INTERRUPTION OF THE STUDY

Your participation in this research programme is completely voluntary and you may withdraw from the study at any time by notifying the Investigator. In this case the data collected until the moment of withdrawal will not be considered for the final analysis.

INFORMATIONS ABOUT THE RESULTS OF THE STUDY

If you wish, the results of the study and in particular those concerning your operation may be communicated to you at the end of the study.

FURTHER INFORMATIONS

For further information and communications during the study the following staff will be available:

Dr. Med. D'Avino Serena 3315618724 serena.davino@guest.policlinicogemelli.it

Dr. Med. Cammertoni Federico 3292060538 federico.cammertoni@policlinicogemelli.it

The protocol of this study has been examined and approved by the Territorial Ethics Committee (CET) Lazio Area 3. The CET has, among other things, verified the compliance of the study with the Rules of Good Clinical Practice and the ethical principles expressed in the Helsinki Declaration and that safety, rights and your well-being have been protected.

If you wish to report events or facts related to the study you may refer to the CET that approved the study.

DECLARATION OF CONSENT

I DECLARE:

▢ I have received a full explanation from Dr _____ about the request to participate to the research in question, as reported in the information section of which I received a copy on _____

▢ I receveid clear explainations and I understood the nature, aims, procedures, expected benefits, possible risks and drawbacks of this research;

▢ I had the opportunity to ask questions to the investigator of the study and I obtained satisfactory answers;

▢ I had enough time to reflect on the information received;

▢ I had enough time to speak with someone else;

▢ I'm aware that the search can be interrupted at any time;

▢ I have been informed that the results of the study will be presented to the scientific community, protecting my identity in accordance with current privacy legislation;

▢ I'm aware that any choice expressed in this consent form may be revoked at any time and without any justification

▢ I received a copy of this consentment.

_____	_____
Date	Signature of the patient
Date	Signature of the doctor

(If the patient is unable to read or sign, an independent witness from the experimenter and sponsor shall be present during the entire discussion of informed consent. The witness shall personally sign and date the informed declaration of consent after the form itself and any other written information has been read and explained to the subject and the subject has given verbal consent to participate in the study).

In this case:

I, the undersigned ……. testify that Dr ……. explained to Mr ……. the characteristics of the study in question, as reported in the information sheet hier attached and the same, having had the opportunity to ask all the questions he deemed necessary, freely agreed to join the study.

Date……. Signature of the independent witness ……..

Date……. Signature of the doctor ……