Cardiac surgery residents' learning curve of intraoperative transit-time flowmetry and high-frequency ultrasound in coronary artery bypass surgery (LEARNERS study)

12/04/2024

Dear Patient,

At the Fondazione Policlinico A. Gemelli IRCCS we are planning a medical-scientific research entitled ″Cardiac surgery residents' learning curve of intraoperative transit-time flowmetry and high-frequency ultrasound in coronary artery bypass surgery (LEARNERS 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 evaluate the complexity of the learning curve of coronary grafts quality assessment with transit time flowmetry (TTFM) and high-frequency epicardial ultrasonography (HFUS).

In details, we intend to obtain data about the time needed by cardiac surgery residents to master the intraoperative quality assessment techniques which are part of common clinical practice.

YOUR PARTICIPATION TO THE STUDY

The study does not require additional acts besides normal clinical practice. We will analyze data already stored in the hospital informatic database and collected during the common clinical procedures. In particular, we will collect:

- *anamnestic data (age, sex, coronary artery disease description);*
- *Intraoperative data (day and kind of surgery, surgery length, cardiopulmonary bypass time, cross-clamp time);*
- *data about diagnostic procedures (intraoperative echographic and flowmetric measurements).*

The study will last four months (three months for patients enrollment and data collection and one month for statistical analysis and scientific paper writing) and 80 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 direct benefits for you, but your participation will allow us to acquire additional information 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 program 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 INFORMATION

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

- Dr. Marcolini Alberta (3388257316 – alberta.marcolini@guest.policlinicogemelli.it)
- Dr. 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 contentment.

_____ _____

Date Signature of the patient

Date Signature of the doctor