INFORMED CONSENT FORM

STUDY OF PERIOPERATIVE PLASMA LEVELS OF ENDOTHELIAL GLYCOCALIX MARKERS IN PATIENTS UNDERGOING COLON SURGERY.

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Centre: Lluís Alcanyís Hospital, Xàtiva.

INFORMATION FOR PARTICIPANTS

Introduction: We are writing to you to inform you about a research study in which you are invited to participate. The study has been approved by an ethics committee. Our intention is that you receive correct and sufficient information so that you can decide whether or not to accept to participate. in this study. To do this, read this information sheet carefully and we will clarify any doubts that may arise. In addition, you can consult with the people you consider appropriate. Voluntary participation We invite you to participate in the study because you are going to be intervened colorectal surgery You should know that your participation in this study is voluntary and that you can decide NOT to participate. cipate If you decide to participate, you can change your decision and withdraw consent at any time, without altering your relationship with your doctor or affecting your health care in any way.

Objective of the study: This research project is aimed at studying the blood levels of certain vascular wall damage markers during the perioperative period of colorectal surgery, and to analyze whether they are related to different patient-dependent parameters (age, sex and associated comorbidities).) and the surgical intervention (surgical time, approach route, type of surgery...). It is also desired to analyze the relationship of said markers of vascular damage with the clinical evolution of the patient; as well as its relationship with other blood markers used in routine clinical practice that indicate a possible postoperative complication. This study is of great pathophysiological and clinical interest, since the correlation of these markers with postoperative clinical evolution is currently unknown, since there is no published article that analyzes the relationship of these markers of vascular damage in patients undergoing colorectal surgery.

Description and activities of the study: This study is aimed at patients who are going to undergo colorectal surgery, either urgently or scheduled. In order to carry out this study, a total of 80 patients will be included. This is an observational study, which consists of collecting health data from their clinical history, and the results of complementary tests carried out during hospital admission. Taking part in this study does NOT change the treatment you are receiving or will receive in the future. Postoperative clinical follow-up will NOT be modified, and the same measures will be carried out as in normal clinical practice. Participation in the study does NOT imply attending more visits than usual or more examinations than usual. In routine clinical practice, we perform

control blood tests to measure certain markers related to the patient's postoperative clinical course. Participating in this study only means carrying out these same tests performed on a regular basis, serially at 5 times: preoperatively, at 2h, 6h, 24h and 48h after completing the surgery, respectively. To include the total of 80 patients who underwent colorectal surgery in this study, we will need approximately 1 year.

Risks and inconveniences derived from the participation in the study: Participation in the study will NOT pose any additional risk to you. Blood tests are routinely performed during postoperative follow-up, even if they do not participate in the study. Participation in the study will only entail the inconvenience of performing these analytics serially at the aforementioned times (preoperatively, at 2h, 6h, 24h and 48h after the end of the surgery). In the subsequent postoperative days (3rd postoperative day and successive) blood tests will be performed as necessary, according to normal clinical practice. Blood samples: 5 blood samples will be obtained and the amount extracted in each analysis will be approximately 25 ml of blood. For most people, needle sticks for blood collection are not a problem. However, sometimes they can cause bleeding, bruising, discomfort, infection and/or pain at the point of blood collection. You may also feel dizzy.

Possible benefits: Since this is a purely observational study, no direct benefit is expected from your participation in the study. However, the knowledge obtained thanks to the studies carried out from their samples and many others can help medical advancement and, therefore, other people. You will not receive any economic benefit for the donation of the samples and the transfer of the data provided, nor will you have rights over possible commercial benefits of the discoveries that may be achieved as a result of the research carried out.

Contact in case of doubts: If during your participation you have any doubts or need more information, please contact: Nuria García del Olmo. Medical specialist in General and Digestive Surgery at Hospital Lluís Alcanyís. Phone: 619660434. Email: nuriagarciadelolmo@gmail.com.

Expenses and economic compensation: Participating in the study does NOT entail any expense for the patient. The investigator and the hospital do NOT receive any financial compensation for conducting the study. This study is carried out solely for academic and scientific purposes, without any financial remuneration.

Protection of personal data: Both the researcher and the Hospital Center will ensure that the principles contemplated in the data protection regulations, both national and European, are complied with. The researcher and the Hospital Center will comply with the data protection regulations:
- Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 (RGPD) regarding the protection of natural persons with regard to to the processing of personal data and the free circulation of these data
- Organic Law 3/2018 of December 5, Protection of Personal Data and guarantee of digital rights (LOPDPGDD) and any other implementing regulations.

At all times, the confidentiality of your data will be maintained. During your participation in the study you will be identified by a code and neither the investigator nor the hospital will transfer any information that could directly identify you. The list that relates the identification code with the data that identifies you (name, surname, medical record number,...) is kept confidential in your health center. Access to your personally identifiable information will be restricted to the study physician/collaborators.

Future use of data in research: The Center and the researcher are obliged to keep the data collected for the study according to the legal deadlines established in the regulations. The researcher for at least 25 years after the end of the study (according to clinical trials regulations) and the center for the time necessary to provide adequate care (according to regulations governing clinical history).

Collection and use of biological samples: Your participation in this study entails the collection and use of biological samples for research purposes, for which Law 14/2007 on biomedical research and Royal Decree 1716/2011 will be observed, regulations that guarantee respect to the rights that assist you. By signing this document, reviewed and favorably evaluated by the Research Ethics Committee of the Hospital that has approved this study, you agree to the use of your samples for the purposes of this study. The samples will be associated with a code that can only be related to their identity by authorized personnel (principal investigator/collaborators), in the same way as previously explained with the data obtained during the study. Once the study is finished, the remaining samples will be destroyed.

INFORMED CONSENT FOR THE PARTICIPANT

Title of the study: Study of perioperative plasma levels of endothelial glycocalyx markers in patients undergoing colon surgery".

I, [name and surname of the participant]

☐ I have read the information sheet about the study.
☐ I have been able to ask questions about the study
☐ I have received enough information about the study
☐ I have talked with the principal investigator/collaborators
☐ I understand that my participation is voluntary
☐ I understand that I can withdraw from the study:
- Whenever I want
- Without need to give an explanation
- Without this affecting my medical care

I will receive a signed and dated copy of this information sheet and informed consent. I freely give my agreement to participate in the study

Signature of the participant Signature of the investigator/collaborator

Date: ____ /____/____ Date: ____/____/____

Note: When IC is obtained from people with modified capacity to give their IC, the legal representative, family member or de facto related person must sign