PATIENT INFORMATION DOCUMENT

Clinical Trial Of Safety Of Robot-assisted Thoracic Approach Versus Open Transthoracic Esophagectomy in Esophageal Cancer (CIR·ROB trial)

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Protocol ID: HUB-CIR-ROB-2020-01

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INTRODUCTION

We turn to you to inform you about a research study in which you are invited to participate. The study has been approved by the relevant Ethical Committee for Clinical Research in accordance with current legislation. We intend you to receive the correct and sufficient information so that you can decide whether or not to participate in this study. To do this, please read this fact sheet carefully and we will clarify any doubts that may arise. In addition, you can consult with the people you deem appropriate.

VOLUNTEER PARTICIPATION

You should know that your participation in this study is voluntary and that you may decide not to participate or change your decision and withdraw consent at any time, without altering your relationship with your doctor or harming your treatment.

STUDY OVERVIEW

The study aims to determine whether the robot thoracic approach decreases postoperative complications (especially respiratory complications), in the short and medium term, compared to the classic thoracic approach (open approach) in esophageal cancer surgery.

The surgical intervention involves removing the esophagus to eliminate tumour injury and removing the corresponding lymph nodes. The stomach is prepared to then bind it to the esophagus to rebuild the digestive transit. This intervention is very complex and it is likely that a blood transfusion and/or blood products may be necessary during surgery and/or in the postoperative period with the risks of infections transmission or other complications that may arise.

A total of 108 participants are expected to be included in this study. If you decide to participate, a first visit will be conducted to verify that you can meet the criteria to participate in the study. Demographic and medical history data will be collected during this visit. Tests will be requested for preoperative evaluation.

Once included in the study, you will be randomly assigned to one of the two established groups. One of them (control group) will perform the usual treatment of patients undergoing this intervention. This consists of an open thoracic approach (right thoracotomy) and abdominal approach by laparoscopy. In the second (study group), the thoracic approach will be carried out by robot, with abdominal approach by laparoscopy (just like the control group). Both surgical techniques are used in our usual clinical practice of the General and Gastrointestinal Surgery Department of the Bellvitge University Hospital.

Regardless of the approach to which you have been assigned, the current protocol of the Esophageal-Gastric Surgery Unit for postoperative care will be followed. Any postoperative complications will be recorded, as well as the treatment offered for the resolution of the same.

The expected duration of follow-up of the study will be 3 months after surgery. Control visits will be made at external consultations of our centre: at 14±2 days (2 weeks after discharge), 28±3 days (1 month after discharge), 56±3 days (2 months) telematically, and at 84±3 days (3 months) after hospital discharge. Nutritional, analytical and clinical data, as well as their quality of quality of life after surgery, will be collected during visits. Any complications presented after discharge will be recorded, the treatment offered for resolution, and the number of re-entry (if any) will be recorded.

After the follow-up period has ended and after the analysis of the results, an extension study will be evaluated to assess survival at 3 and 5 years after surgery. The patient will be offered the opportunity to participate in such a study, knowing that their participation is voluntary and that they may decide not to participate or change their decision without altering the relationship with their doctor or any harm in their treatment.

BENEFITS

Your participation in this study would contribute data to increase knowledge about the benefit of robotic surgery in decreasing postoperative complications in patients undergoing esophageal cancer surgery. The results could contribute to a change in standard clinical practice.

RISKS

The risks of the intervention stem from the possible complications of the surgery itself. Before surgery, different tests are performed to prevent any possible complications. Despite prevention and the proper choice and realization of the technique, some complication may arise, such as:

- General complications common to any complex surgery: urinary tract infection, respiratory infection, phlebitis, wound infection, cardiorespiratory and renal complications, prolonged pain in the area of operation, temporary digestion disorders, as main.

- Specific complications of the intervention that you have to perform: there are a set of rare but serious complications, such as bleeding, intra-abdominal and intrathoracic infection (mediastinitis), intestinal obstruction, fistula of the gastric stump or esophageal-gastric suture and/or dehiscence of the suture.

These complications are usually resolved with medical treatment (drugs, serum therapy), but may sometimes require an invasive procedure (placement of drains) or reintervention, usually emergency surgery, and can become so severe that they even lead to the patient's death. If you need more information, ask your doctor to clarify any questions you may have.

CONFIDENTIALITY AND DATA PROTECTION

The processing, communication and transfer of personal data of all participating subjects shall comply with the provisions of Organic Law 3/2018 of 13 December on the protection of personal data. In accordance with the above legislation, you can exercise the rights of access, modification, opposition and cancellation of data, for which you must contact your study doctor. The data collected for the study will be identified by a code and only your collaborating study doctor will be able to relate such data to you and your medical history. Only data collected for the study that will in no case contain information that can directly identify you, such as first and last name, initials, address, social security number, etc., will be transmitted to third parties and other countries. In the event of this assignment, it will be for the same purposes of the study described and guaranteeing confidentiality at least with the level of protection of the legislation in force in our country.

Access to your personal information will be restricted to the study physician/collaborators, health authorities, the Ethical Committee of Clinical Research and personnel authorized by the promoter, when they need it to check the data and procedures of the study, but always maintaining the confidentiality of them in accordance with current legislation.

ECONOMIC COMPENSATION

The Promoter of the study is responsible for managing the financing of the same. Your participation in the study will not incur any expenses.

OTHER RELEVANT INFORMATION

Any new information regarding the surgery performed in the study that may affect your willingness to participate in the study, which is discovered during your participation, will be communicated to you by your doctor as soon as possible. If you decide to withdraw consent to participate in this study, no new data will be added to the database and may require the destruction of all previously retained identifiable samples to prevent further analysis.

You should also know that you may be excluded from the study if the promoter and/or researchers of the study deem it appropriate, either for safety reasons, such as pregnancy*, for any adverse events caused by the medication under study or because they consider that the established procedures are not being complied with. In either case, you will receive an adequate explanation of the reason for your withdrawal from the study.

*NOTE: You should know that if a pregnancy occurs during your participation in the study, you should tell your doctor immediately to receive appropriate medical assistance and assess your withdrawal from the study.

By signing the accompanying consent sheet, you agree to comply with the study procedures set out above. When you finish your participation, you will receive the best treatment available and have your doctor consider the most appropriate for your condition.

INFORMED CONSENT DOCUMENT

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I …….

I have read the information document that has been given to me.

I have been able to ask questions about the study.

I have received enough information about the study.

I have spoken to (name of the researcher): ……

I understand that my participation is voluntary.

I understand that I can withdraw from the study:

- 1st Whenever I want
- 2nd With any reason
- 3rd without affecting my medical care.

I freely agree to participate in the study and I consent to the access and use of my data under the conditions detailed in the information document.

I will receive a signed and dated copy of this informed written consent document

I freely agree to participate in the study.

YES □ NO □

Patient's signature: Researcher's signature:

Name: Name:

Date: Date: