INFORMATION AND INFORMED CONSENT DOCUMENT

PROJECT title: "PROFUGO STUDY: PREDICTIVE Model for the Early Diagnosis of Anastomotic LEAK after esophagectomy and gastrectomy"

Name and surname of the participant: _____

1. Introduction

We are writing to you to invite you to participate in a research project that we are carrying out in our hospital and in other centers in the national territory and for which your participation is important to obtain the knowledge we need, but before making a decision you must:

- Read this entire document
- Understand the information contained in the document
- Ask all the questions you consider necessary
- Consult with your trusted doctor-person
- Make a thoughtful decision
- Sign the informed consent, if you finally want to participate.

If you decide to participate, you will be given a copy of this document and the signed consent. Please keep them in case you need them in the future.

2. Why are you being asked to participate?

Your collaboration is requested as you are over 18 years of age and you are going to undergo surgery to remove the diseased part, in order to later restore the continuity of the digestive tract in your case. You will receive adequate and complementary information about the surgical procedure from your surgeon.

3. What is the object of this study?

The study has the intention and objective of evaluating postoperative results and trying to establish a predictive model for the early diagnosis of anastomotic leak or fistula after resection surgery of the stomach and esophagus based on analytical and clinical data. This is intended to establish a model that allows us to approach the earliest diagnosis of this possible complication and thus be able to offer a faster and more effective treatment.

4. What do I have to do if I decide to participate?

Remember that your participation is voluntary and if you decide not to participate this will not affect your attendance or your relationship with the researcher and his team.
If you decide to participate and as you have been informed, your constants and clinical situation will be evaluated daily according to the usual clinical care and blood tests will be taken similar to those that would be performed if you did not participate in this study.

5. What risks or inconveniences does it entail?

As mentioned before, this study intends to evaluate the postoperative results and try to establish a predictive model for the early diagnosis of anastomotic leak or fistula after resection surgery of the stomach and esophagus based on analytical and clinical data. This is intended to establish a model that

allows us to approach the earliest diagnosis of this possible complication and thus be able to offer a faster and more effective treatment.

To do this, his constants and clinical situation will be evaluated daily according to the usual clinical care and blood tests will be taken similar to those that would be performed if he does not participate in this study, in which different values will be determined in relation to the inflammation and infection used. routinely in routine clinical practice.

Risk of blood draw: Blood will be drawn through a needle inserted into one of the veins in your arm. This procedure carries a number of associated risks, including the following: pain, bruising, redness, bleeding, infection, and fainting. However, these risks associated with the extraction of the sample are no more than those associated with the extraction of a blood sample for a routine analysis.

6. Will I get any benefit from my participation?

As it is a research study aimed at generating knowledge, it is likely that you will not obtain any benefit from your participation, although you will contribute to the advancement of knowledge and social benefit.

You will not receive any financial compensation for your participation.

7. How will my personal data be managed?

All the information collected will be treated in accordance with the provisions of Organic Law 15/99, on the protection of personal data. No personal data will be included in the study database: neither your name, nor your medical record number, nor any data that can identify you. You will be identified by a code that only the research team will be able to associate with your name.

Only the research team will have access to your medical record data and no one outside the center will be able to consult your record.

To exercise your right of access, rectification, cancellation and opposition regarding your data obtained during the study, you must contact the principal investigator.

The conclusions of the study will be presented at congresses and scientific publications, but they will always be done with grouped data and nothing that can identify you will ever be disclosed.

8. Who finances the study?

There is no funding for the realization of this project.

9. Will I be informed of the results of the study?

You have the right to know the results of this study, both the general results and those derived from your specific data. You also have the right not to know such results if you wish. For this reason, in the informed consent document we will ask you which option you prefer. In case you want to know the results, the researcher will send you the results.

10. Can I change my decisión to participate in it?

As noted, your participation is completely voluntary, you can decide not to participate or withdraw from the study at any time without having to give reasons and without this affecting your health care. You just need to tell the principal investigator of the study your intention.

If you wish to withdraw from the study, the collected data and biological samples not used at that time will be deleted.

11. What happens if I have any questions during my participation?

In case of doubt or for any query related to your participation, you can contact the researcher in charge, Dr. _____ in the General Surgery Service of the Hospital _____ in the morning or by email at the address: _____

Thank you very much for your attention, if you finally wish to participate, please sign the attached consent document.

INFORMED CONSENT DOCUMENT

PROJECT title: "PROFUGO STUDY: PREDICTIVE Model for the Early Diagnosis of Anastomotic LEAK after esophagectomy and gastrectomy"

I, ...(name and surname of the participant)

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

I have been able to ask questions about the study and have received enough information about the study.

I have spoken with: .... (name of investigator)

I understand that my participation is voluntary. I understand that I can withdraw from the study:

1) whenever you want
2) without having to explain
3) without this affecting my medical care

I freely give my consent to participate in the study

I want to be informed about the results of the study: yes no (check all that apply)

I have received a signed copy of this Informed Consent.

Participant's Signature: .... Date:..... .....

I have explained the nature and purpose of the study to the named patient

Investigator's Signature:..... ..... Date:..... .....

INFORMED CONSENT OF THE LEGAL REPRESENTATIVE

Title of the research project: "PROFUGO STUDY: Predictive Model for the Early Diagnosis of Anastomotic LEAK after esophagectomy and gastrectomy"

I, ……

in the capacity of: ……

from: ……

I have read the information sheet above.

I was able to ask questions about the study.

I have received enough information about the study.

I have spoken with ……

I understand that participation is voluntary.

I understand that you can withdraw from the study:

- Whenever you want.
- Without having to explain.
- Without this affecting his medical care.

I understand that this material appears in reports and journal articles in medical journals.

I understand that:

- My name will not be published.
- The material will not be used for advertising or packaging.
- The material will not be used out of context.

In my presence, it has been given to

…… ……

…… all pertinent information tailored to your level of understanding and you agree to participate .

And I agree that …….. participate in the study.

Signed: …….. Date……..