PATIENT INFORMATION SHEET FOR RESEARCH PROJECTS

(Version 2.0 31/10/2022)

STUDY TITLE: 3D image processing and reconstruction for the assessment of tumor infiltration in colon cancer: prospective observational non-randomized trial

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INTRODUCTION
We are writing to inform you about a study in which you are invited to participate. The study has been approved by the Research Ethics Committee of the Balearic Islands, in accordance with current legislation, and is being conducted in accordance with the principles set out in the Helsinki declaration and the standards of good clinical practice.
Our intention is only that you receive correct and sufficient information so that you can evaluate and judge whether or not you want to participate in this study. To this end, please read this information sheet carefully and we will clarify any doubts you may have after the explanation. In addition, you can consult with the people you consider appropriate. If you have any doubts, please contact Sebastián Jerí Mc Farlane.

GENERAL DESCRIPTION
Surgical treatment of locally advanced colon (suspected infiltration of neighboring structures) requires interventions with a high rate of complications and mortality. The most important prognostic factor for survival is to achieve surgery with infiltration-free margins, known as surgery with R0 resection.
Despite imaging and intraoperative technological advances, infiltrated surgical margin rates remain high for this type of tumor, due to the complexity of the procedures. The preoperative surgical strategy is important in deciding how to surgically approach the tumor and a change in surgical strategy should be made to obtain an R0 resection.
If the surgeons who are going to operate could have a preoperative 3D reconstruction of the case, this would help them to have a better idea of the lesion and thus perform a complete resection and be able to decrease the percentage of complications.
In addition, the surgeon can practice the upcoming surgery on the 3D impression or visualize it on the computer to virtually walk through and experiment with the anatomical part they will be facing on the operating table days later.
As these are surgeries that sometimes require resection of multiple structures, the preoperative strategy is essential to decide which organs should be removed together with the colon cancer. Preoperative simulation using 3D printing could help to get a more accurate idea of the structures involved and whether a more extensive resection is necessary.
If this preoperative simulation using reconstruction and 3D printing proves useful, patients' survival and quality of life could benefit.
The risks of this study are the same as the risks derived from the surgery itself, which we want to assess whether it is possible to reduce with the use of reconstruction with 3D models.
A computed tomography (CT) scan will be performed to define the colon tumor (staging) prior to surgery. With this CT scan, the 3D model reconstruction is performed. Subsequently, in a multidisciplinary committee, the CT result is used to decide what type of surgical intervention will be performed to obtain an adequate oncologic resection. Then, the tumor is analyzed with the anatomic pathology team and compared with the 3D and CT models performed.
If you decide to withdraw your consent to participate in this study, no new data will be added to the database and you may require the destruction of all identifiable samples previously retained to prevent further analysis, although those responsible for the study may continue to use the information collected about you up to that point, unless you expressly object.
You should also be aware that you may be withdrawn from the study if those responsible for the study deem it appropriate, either for safety reasons, because of any adverse event arising from

the study medication or because they consider that you are not complying with the established procedures. In either case, you will receive an adequate explanation of the reason for your withdrawal from the study.
If you are withdrawn from the study for any of the above reasons, your physician will prescribe an appropriate treatment for your condition.
By signing the attached consent form, you agree to comply with the study procedures outlined to you.

BENEFITS AND RISKS OF PARTICIPATING IN THE STUDY
This study will make it possible to assess whether 3D models in locally advanced colon cancer (right, transverse or left) are useful to improve the care provided to patients, improve surgical indications, and assess the anatomical variants of the blood vessels that irrigate the colon and thus try to reduce the rate of complications in this type of surgery.
There are similar studies previously performed in few patients where a benefit has been seen in having a better idea of the lesion to be operated on.
There are no risks associated with CT since this is a mandatory step in the staging of colon tumors and should be performed in all patients who wish to treat their disease.
Information will be collected for 1 year and a half and compliance with the General Data Protection Regulation will be guaranteed.

CONFIDENTIALITY
Data controller: Sebastián Jerí Mc Farlane (Colorectal Surgery Unit, Hospital Universitario Son Espases), Telephone: +34 871 20 50 00, E-mail: Sebastian.jeri@ssib.es
Recipients of the information: Principal investigator and collaborators of the center.
Maximum period of conservation of the data: 5 years.
The processing, communication, and transfer of personal data of all participating subjects will comply with the provisions of the Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights.
In accordance with the provisions of the aforementioned legislation, you may exercise your rights of access, rectification, deletion, opposition, limitation of data processing, including to transfer your data to an authorized third party (portability), for which you should contact the principal investigator responsible for processing at the following addresses (Carretera de Valldemosa 79, Palma de Mallorca, Spain 07120 - Servicio de Cirugía General y del Aparato Digestivo).
Your data will be processed by computer and will be incorporated into an automated system of personal data that complies with all the security measures of restricted access for the purpose described in this document.
To guarantee the confidentiality of the information obtained, coding or pseudo-anonymization will be done to your data and the sample will be identified by a code and only the principal investigator will be able to relate these data to you and your medical history. Therefore, your identity will not be disclosed to any person except in case of medical emergency, health administration requirement or legal requirement.
Only the essential data necessary to carry out the study will be transmitted to third parties and to other countries, and in no case will they contain information that can directly identify you, such as name and surname, initials, address, Social Security number, etc. If this transfer occurs, 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 doctor, health authorities, the Research Ethics Committee of the Balearic Islands, and authorized personnel, when required to check the data and procedures of the study, but always maintaining the confidentiality of the same in accordance with current legislation.
You are also informed that you can make any inquiry about this treatment before the Delegation of Data Protection of the Health Service of the Balearic Islands which has its headquarters at Calle de la Reina Esclarmunda, 9, Palma (Balearic Islands) and its contact email is dpd@ibsalut.es.
In any case, you can contact the Spanish Data Protection Agency for any claim arising from the processing of your personal data.

FINANCIAL COMPENSATION
Your participation in the study will not involve you in any costs.

Your physician will not receive financial compensation for your participation in this study and has declared that there is no conflict of interest.

VOLUNTARY PARTICIPATION

You should be aware that your participation in this study is voluntary and that you may decide not to participate or to change your decision and withdraw your consent at any time, without giving any explanation, without altering your relationship with your physician or the treatment you are to receive.

If you decide to revoke your consent, no new data will be collected, no new sample analysis will be performed, but this revocation will not affect the research conducted so far.

THANK YOU

Whatever your decision, both the research team would like to thank you for your time and attention. You are contributing to the better understanding and care of your disease, which in the future may benefit a multitude of people.