INFORMATION SHEET FOR PARTICIPANTS IN RESEARCH STUDIES WITHOUT SAMPLES

Study Title: Abdominal drainage in the postoperative period of liver transplantation (DRALIT): Randomized multicenter clinical trial.
Principal Investigator, service/unit and centre: Victor Lopez Lopez. General Surgery and Digestive System Service. University Clinical Hospital "Virgen de la Arrixaca", Ctra. Murcia-Cartagena s/n, CP 30120, El Palmar-Murcia,
Promoter/financier: Transplant Unit. General Surgery and Digestive System Service. University Clinical Hospital "Virgen de la Arrixaca"
Version number and date: v1.2 05/24/2022

INTRODUCTION

Considering the disease or process that you suffer from, we are writing to you to inform you about a study in which you are invited to participate. Our intention is that you receive the correct and sufficient information so that you can evaluate and judge whether or not you want to participate in this study. Before deciding whether you want to participate or not, please read this document carefully, which includes information about this project. You can ask all the questions that arise and request any clarification on any aspect of it. We will clarify any doubts that may arise at any time. In addition, you can consult with the people you consider appropriate.

The project has a favorable report from an accredited Research Ethics Committee in Spain.

VOLUNTARY PARTICIPATION

You should know that your participation is voluntary and that you can decide not to participate or change your decision and withdrawconsent at any time, without altering the relationship with your doctor or causing any damage to your treatment.

PURPOSE AND PROCEDURES OF THE STUDY:

We request your participation in this research project whose main objective is to deepen the knowledge of the use of abdominal drains in the immediate postoperative period of liver transplantation.

The main objective of the study is the evaluation of postoperative complications of liver transplantation and their relationship with the use of abdominal drains. It is wanted to evaluate if they suffer some type of relation with the drainage. The evaluation of the quality of life in the postoperative period in both groups and its relationship with the hospital stay is also the objective of the study.

EXPECTED BENEFITS:

It is possible that your participation in this study will not result in direct benefit, although your participation in this study will allow you to provide relevant information regarding abdominal drains in liver transplantation.

The need for the use of abdominal drains in the postoperative period of liver transplant patients and their relationship or not with the presence of postoperative complications is being studied.

The placement or not of the abdominal drain can have in both cases certain complications in an exceptional way (bleeding, biliary fistula, infections,...). A specific civil liability insurance policy has been contracted for the risks arising from this study.

RIGHT TO REVOCATE CONSENT

If you change your mind regarding the data provided, you have the right to request its destruction or anonymization, through your doctor/researcher/principal investigator. However, you should know that the data

obtained in the analyzes carried out up to that moment may be used for the purposes requested and may be kept in compliance with the corresponding legal obligations.

CONFIDENTIALITY/PERSONAL DATA PROTECTION:

Your data will be associated with a code (encrypted) or anonymised. Process by which it is not possible to establish a relationship between a data or sample and the subject to which it refers. In addition, the data not associated with an identified or identifiable person by means of a code that allows the reverse operation. Only authorized personnel (liver transplant unit surgeons) may link the information derived from the analyzes performed with information about your identity.

Organic Law 3/2018 of December 5, on the Protection of Personal Data and guarantee of digital rights and Regulation (EU) 2016/679 of the European Parliament and of the Council of December 27 are fully applicable to this study. April 2016 Data Protection (RGPD). Therefore, it is important that you know the following information:

- Your personal data will be processed for the purpose indicated in the document to be signed and will be kept for the years necessary to comply with current applicable regulations.

- The Data Controller is the "Virgen de la Arrixaca" University Clinical Hospital (Area I de Salud-Murcia/Oeste), whose Data Protection Delegate (DPD) is Ms. Elena García Quiñones with address at Servicio Murciano de Salud, C. / Central nº 7, Habitamia I Building, 30100, Espinardo-Murcia (email: dpd-sms@carm.es).

- The legal basis that legitimizes the treatment is your consent.

- Applicable regulations: Regulation (EU) No. 536/2014 of the European Parliament and of the Council, of April 16, 2014, on clinical trials of medicinal products for human use, and by which Directive 2001/20/EC is repealed; Organic Law 3/2018, of December 5, on the Protection of Personal Data and Guarantee of Digital Rights, Law 14/2007, of July 3, on Biomedical Research; Royal Legislative Decree 1/2015, of July 24, approving the revised text of the Law on guarantees and rational use of medicines and health products; Law 44/ Law 44/2003, of November 21, on the organization of health professions, as well as Law 14/1986, of April 25, on General Health, Law 41/2002, of November 14, on autonomy of the patient, and other current legislation in health matters.

- Your data will not be transferred, except in cases required by law or in cases of medical emergency. However, at any time you can revoke the consent given, as well as exercise your rights of access, rectification, deletion, opposition, limitation of treatment and portability, to the extent applicable, through written communication to the Data Controller of the following way specifying your request, together with your DNI or equivalent document:

    - **Principal Investigator of the study / Coordinator**: Victor Lopez Lopez / Alvaro Cerezuela Fernandez de Palencia
    - **Home**: "Virgen de la Arrixaca" University Clinical Hospital, Ctra. Murcia-Cartagena s/n, CP 30120, El Palmar-Murcia,

- Likewise, we inform you of the possibility of filing a claim with the Spanish Data Protection Agency (C/Jorge Juan, 6 Madrid 28001)www.agpd.es

Access to your personal information will be restricted to the study doctor/collaborators, Health Authorities in matters of inspection, the Clinical Research Ethics Committee, when required to check the data and procedures of the study, but always maintaining their confidentiality.

The data collected for the study will be identified by a code, so that information that can identify you is not included, and only your study doctor / collaborators will be able to relate said data to you and your medical history.

The associated data will be kept under adequate security conditions and it is guaranteed that the subjects cannot be identified through means considered reasonable by persons other than those authorized.

Some additional data may be required. In that case, your doctor will contact you to request your collaboration again. You will be informed of the reasons and your consent will be requested again (see yes/no option at the bottom of the sheet).

From said data, scientific communications can be prepared to be presented at congresses or scientific journals, always maintaining the confidentiality of your personal data at all times.

You are informed that in accordance with the provisions of the seventeenth additional provision of Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights, as well as article 89 of the Regulation (EU) 2016/679, in the event that your data is processed for public health research purposes and, in particular, biomedical research, the following will be carried out:

- Carry out an impact assessment that determines the risks arising from the treatment in the cases provided for in article 35 of Regulation (EU) 2016/679 or in those established by the control authority. This evaluation will specifically include the risks of re-identification linked to the anonymization or pseudonymization of the data.

- Submit scientific research to quality standards and, where appropriate, to international guidelines on good clinical practice.

- Adopt, where appropriate, measures aimed at ensuring that researchers do not access identification data of interested parties. In the event that this separation between the data and the researcher cannot be guaranteed, an express commitment to confidentiality is guaranteed by the researcher as well as not to carry out any re-identification activity. Specific security measures will be adopted to prevent re-identification and access by unauthorized third parties.

Only the data collected for the study will be transmitted to third parties, which in no case will contain information such as name and surname, initials, address, or social security number. In the event that 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. If you want to know more about it, you can consult with the principal investigator or contact the Data Protection Delegate.

Appropriate measures will be adopted to guarantee the protection of your privacy and your data will not be cross-referenced with other databases that could allow your identification.

IMPLICATIONS OF THE INFORMATION OBTAINED WHEN ANALYZING THE DATA

In the event that you request it, you may be provided with specific information about the research study in which you have participated, as well as the general results of this study.

In the event that this study obtains data that could be clinically or genetically relevant for you, and of interest to your health or that of your family, you may request that they be communicated to you by your trial doctor if you indicate so in the box that appears at the end of this document. However, if the patient had indicated his refusal and when this information, in the opinion of the responsible physician, is necessary to avoid serious damage to his health or that of his biological relatives, a close relative or a representative will be informed, after consulting to the Healthcare Ethics Committee of the center. The communication of this information will be carried out by professionals who will be able to adequately explain its relevance and the options that may arise.

In the case of a minor donor, once they reach the age of majority, they will have the right to receive this information and to revoke their consent. In the event that she does not exercise it, it will be considered that the current document is still in force.

FUTURE RESEARCH

I authorize the possible reuse of personal data for health and biomedical research purposes for purposes or research areas related to this study.

INFORMED CONSENT SHEET

Study Title: Abdominal drainage in the postoperative period of liver transplantation (DRALIT): Randomized multicenter clinical trial.
Principal Investigator, service/unit and centre: Victor Lopez Lopez. General Surgery and Digestive System Service. University Clinical Hospital "Virgen de la Arrixaca", Ctra. Murcia-Cartagena s/n, CP 30120, El Palmar-Murcia,
Promoter/financier: Transplant Unit. General Surgery and Digestive System Service. University Clinical Hospital "Virgen de la Arrixaca"
Version number and date: v1. 12/16/2021

Participant/patient data
Name

_____

Researcher or person providing the information
Name

_____

1. I have read, been informed and understand the content of this information sheet, which I certify with my signature as proof of my consent to everything contained therein.

2. I understand that my participation is voluntary and free of charge and I understand that I can request the revocation of this consent at any time, without having to offer explanations and without this affecting my present and/or future medical care.

1. I want the study doctor to communicate information derived from the research that may be relevant and applicable to my health or that of my family members:

   · YES · NO Telephone or contact e-mail……

2. I consent to the storage of the associated data for future research under the conditions explained in this information sheet.

   · YES · NO

3. I consent to be contacted in the event that additional information is needed.

   · YES · NO Telephone or contact e-mail……

Date: Signature of Participant/Patient

Date: Signature of the Investigator or person providing the information

REVOCATION OF CONSENT

I, Mr/Ms..... revoke the consent given on the date and do not wish to continue participating in the study"Abdominal drainage in the postoperative period of liver transplantation (DRALIT): Randomized multicenter clinical trial.".

Patient's signature:

Investigator Signature: Date: