PATIENT INFORMATION SHEET

TITLE OF THE STUDY: "VALUE OF TEMPORARY OCCLUSION OF THE UTERINE ARTERIES IN LAPAROSCOPY MYOMECTOMY"

RESEARCHERS: Dr. Enrique Moratalla Bartolome
CENTER: RAMÓN Y CAJAL UNIVERSITY HOSPITAL

1. INTRODUCTION

The Obstetrics and Gynecology Department of the Ramon y Cajal University Hospital is conducting a study to assess whether performing temporary occlusion of the uterine arteries and utero -ovarian ligaments during laparoscopic myomectomy reduces intraoperative bleeding from this technique and postoperative anemia.

The participant are being asked to participate in this study because the participant will be undergoing a laparoscopic myomectomy at our center. The study has been approved by the Clinical Research Ethics Committee of the Ramón y Cajal University Hospital.

Our intention is that the participant receive correct and sufficient information so that the participant can evaluate and judge whether or not the participant want to participate in this study. To do this, read this information sheet carefully and the investigators will clarify any doubts that may arise after the explanation . In addition, the participant can consult with the people you consider appropriate.

When the participant have read this information and if the participant wish to participate in the study, the participant must sign the informed consent form attached to this document in duplicate.

2.- VOLUNTARY PARTICIPATION

The participant should know that your participation in this study is voluntary and that the participant can decide not to participate or change your decision and withdraw your consent at any time, without altering your relationship with your doctor or affecting your treatment.

3.- OBJECTIVE

The aim of this study is to determine whether patients who underwent laparoscopic fibroid removal and temporary placement of a metallic mechanism (called a “clip”), which acts as a clamp on the uterine arteries and utero-ovarian ligaments, have decreased bleeding during surgery, compared to patients who underwent laparoscopic myomectomy without said clips .

4.- GENERAL DESCRIPTION OF THE STUDY

This is a study in which patients who underwent laparoscopic myomectomy with temporary placement of "clips" in the uterine arteries and utero-ovarian ligaments, which are removed at the end of the intervention, are compared with another control group of patients who underwent laparoscopic myomectomy with the traditional technique (without "clips) usually performed in other centers.

5.- STUDY ACTIVITIES

If the participant participate in the study, the investigators will give the participant this disclosure document to keep and ask the participant to sign an informed consent form, a copy of which will be given to you.

6.- BENEFITS AND RISKS DERIVED FROM YOUR PARTICIPATION IN THE STUDY

The participant are not expected to benefit directly from the results of this research, although others may benefit in the future. The participant will not receive any type of compensation for your participation in this study or derived from its results.
laparoscopic myomectomy surgeries .
The risks of the intervention are those inherent to those of a myomectomy that are detailed in the informed consent for the surgery.
The information obtained from this study may be useful to the scientific community, and the results may be published and contribute to improving the possibilities of treatment.

7.- PROTECTION OF PERSONAL DATA

The treatment, communication and transfer of personal data of all participating subjects will comply with the provisions of the General Data Protection Regulation (RGPD) and the Organic Law Organic Law on Data Protection and Guarantee of Digital Rights (LO 3/2018 PD and GDD) . In accordance with the provisions of the aforementioned legislation The participant can exercise the rights of access, modification, opposition and cancellation of data, limit the treatment of data that is incorrect, request a copy or that the data that the participant have provided for the study be transferred to a third party (portability). To exercise your rights, contact the principal investigator of the study ".

The data collected for the study will be identified by a code and only your study doctor/collaborators will be able to associate said data with the participant and your medical history.

Since May 25, 2018, the new legislation in the European Union on personal data is fully applicable, specifically Regulation 2016/679 of the European Parliament and of the Council of April 27, 2016 on data protection .

Both the Center and the Researcher are responsible for the processing of your data and undertake to comply with current data protection regulations.

April 27, General Data Protection and will be used only for the aforementioned research purposes .

Only the data collected for the study will be transmitted to third parties, which in no case will contain information that can directly identify the participant, such as name and surname, initials, address, social security number, etc.

their confidentiality in accordance with current legislation .

8.-ECONOMIC COMPENSATION

The investigators inform the participant that no fees are expected to be paid to the participant for participation in the study or to the researchers.

9.- CONTACT IN CASE OF DOUBTS

If during your participation the participant have any questions or need more information, please contact:

Dr. Enrique Moratalla Bartolomé, telephone 913368105. Gynecology Service Ramón y Cajal University Hospital.

10.- OBTAINING AND USE OF BIOLOGICAL SAMPLES

The study samples (fibroids) will be identified and sent to the Pathological Anatomy Service for diagnosis, being informed of the result at the post-surgery medical visit , but they will not be used for the purposes of the biomedical research of this study. The confidentiality of the treatment of your samples and associated data will be maintained at the level of protection indicated by the laws in force in our country (Organic Law 3/2018, of December 5, Protection of Personal Data and guarantee of digital rights and Regulation (EU) 2016/679, of April 27, General Data Protection and the terms set forth in Law 14/2007 of Biomedical Research will be complied with .

OTHER RELEVANT INFORMATION

If the participant decide to withdraw consent to participate in this study, no new data will be added to the database.

By signing the attached consent form, the participant agree to abide by the study procedures that have been disclosed to you.

INFORMED CONSENT

TITLE OF THE STUDY: "VALUE OF TEMPORARY OCCLUSION OF THE UTERINE ARTERIES IN LAPAROSCOPY MYOMECTOMY"

I, Ms ,……, with address at .....and ID number..... declare that

I have read the information sheet that was given to me.

I have been able to ask questions about the study.

I have received enough information about the study.

I have been informed by:

....

Dr. Enrique Moratalla Bartolomé

I hereby consent to participate in the aforementioned study.

I understand that my participation is voluntary.

I understand that I can withdraw from the study:

1º Voluntarily whenever I want.

2º Without having to give explanations.

3º Without this affecting my medical care.

I freely give my consent to participate in the study and give my consent for the access and use of my data under the conditions detailed in the information sheet.

Patient Signature :

Name :
Date :

Investigator Signature :

Name : Enrique Moratalla Bartolomé.
Date :

This document is signed in duplicate, keeping one copy for the researcher and the other for the patient.