Pain Evaluation Across Robotic and Laparoscopic Surgery for Colorectal Procedures

(PEARL Study)

IP: Patricia Tejedor Togores

Code: CR001

Date: 1st July 2025

Patient Information Sheet and Informed Consent Form

Patient Information Sheet

Study Title: Pain Evaluation Across Robotic and Laparoscopic Surgery for Colorectal Procedures

Principal Investigator:

Department of General and Digestive Surgery, Hospital General Universitario Gregorio Marañón.

Objective:

This document requests your consent to participate in a study designed to evaluate differences in postoperative pain perception between robotic and laparoscopic approaches for colorectal surgery. The study has been reviewed and approved by the Ethics Committee of Hospital General Universitario Gregorio Marañón.

Study Procedures:

No interventions or tests beyond routine clinical practice will be conducted. If you agree, your treatment details and clinical evolution will be analyzed through your medical records. Additionally, you will be asked to complete validated written questionnaires regarding your quality of life after surgery.

Benefits:

There will be no direct benefit from participating in this study. Both surgical approaches will follow the same therapeutic and analgesic management. However, the information gathered may help improve future postoperative care.

Risks:

There are no additional risks associated with study participation. All surgeries will be performed by expert colorectal surgeons using internationally validated techniques. Postoperative management will remain unchanged from standard care.

Confidentiality:

The study complies with Spanish health laws, the Declaration of Helsinki, and data protection regulations (GDPR 2016/679 and Organic Law 3/2018). Your data will be anonymized and only accessible to the study team, the Ethics Committee, and health authorities. You have the right to withdraw consent at any time without affecting the legality of prior data handling.

You will be assigned a unique study code at data collection. Only the Principal Investigator will have the list linking codes with personal identities. Data will be stored for 7 years, with 4 years dedicated to collection and analysis, and 3 years until publication and subsequent deletion.

Data Controller:

Principal Investigator: Dr. Patricia Tejedor Togores
Email: patricia.tejedor@salud.madrid.org

Your Rights:

You may exercise your rights of access, rectification, erasure, portability, limitation, opposition, and complaint to the Data Protection Officer or the Spanish Data Protection Agency (AEPD).

Informed Consent Form

Study Title: Pain Evaluation Across Robotic and Laparoscopic Surgery for Colorectal Procedures

Sponsor: Dr. Patricia Tejedor Togores

I (Name and Surname):
.....
confirm that I have read the information sheet provided.

I have had the opportunity to ask questions about the study.

I have received sufficient information about the study.

I have spoken with:
.....
(Name of the investigator, to be completed by the participant)

I understand that my participation is voluntary and that I can withdraw from the study at any time without giving reasons and without affecting my medical care.

I freely give my consent to participate in the study.

Participant Signature:
Date:

By the Investigating Team:
Name:
Date:
Investigator Signature:
Date:

This document will be completed in duplicate: one copy for the investigator and one for the participant.