PROMISER Registry

Version 3, March 9, 2026

“PROspective study of MInimally invaSIve abdominal wall hERnia repair”

Protocol Code: PROMISER2026

[REDACTED NAME]

General and Digestive Surgery. Fundación Jiménez Díaz

CONTENTS

SUMMARY

Study Identification

Title:

Prospective study of minimally invasive abdominal wall hernia repair

Code: PROMISER

Version: January 1, 2026

Sponsor:

Research Institute of Fundación Jiménez Díaz, Madrid.

Research Team Responsible:

Principal Investigators:

- [REDACTED NAME]
- [REDACTED NAME]

Co-investigators:

- [REDACTED NAME]
- [REDACTED NAME]
- [REDACTED NAME]
- [REDACTED NAME]

Study Centers:

Hospital Universitario Fundación Jiménez Díaz

Ethics Committee:

CEIm of Hospital Universitario Fundación Jiménez Díaz

OBJECTIVES

Primary Objective:

To investigate the recurrence rate of hernias repaired using these techniques.

Secondary Objectives:

- Determine surgical complications and associated morbidity and mortality
- Assess pain and quality of life
- Investigate reoperation rates
- Describe risk factors for hernia formation
- Define the usefulness of prehabilitation programs

STUDY DESIGN

Prospective observational dynamic cohort.

DISEASE UNDER STUDY

Primary and incisional ventral hernias.

POPULATION

Approximately 80 patients per year.

TIMELINE

Start: March 2026

Total duration: 10 years

INTRODUCTION AND JUSTIFICATION

Ventral and incisional hernias are among the most frequent conditions in general surgery and represent a major public health problem due to their high prevalence, recurrence rates, and impact on quality of life.

Minimally invasive techniques (laparoscopic and robotic) have significantly changed surgical management, showing advantages such as fewer complications, less pain, and shorter hospital stays.

However, they also have limitations, including higher costs, longer operative times, and a significant learning curve.

This study aims to evaluate recurrence, pain, quality of life, complications, and long-term outcomes.

HYPOTHESIS

This is a descriptive study aiming to estimate 5-year recurrence with ±4% precision.

PRIMARY OBJECTIVE

Evaluate recurrence rate after minimally invasive abdominal wall surgery.

SECONDARY OBJECTIVES

- Surgical complications and morbidity/mortality
- Pain and quality of life
- Reoperation rates
- Risk factors
- Role of prehabilitation

STUDY DESIGN

Prospective observational cohort.

SUBJECT SELECTION

Adult patients undergoing minimally invasive surgery.

INCLUSION CRITERIA

Patients indicated for minimally invasive abdominal hernia repair.

EXCLUSION CRITERIA

- Age <18
- Refusal to participate
- Only inguinal hernias
- Not candidates for minimally invasive surgery

SAMPLE SIZE

Approximately 400 patients over 5 years.

STUDY DEVELOPMENT

Includes preoperative, 3-month, 12-month, and long-term follow-up visits.

VARIABLES

Demographics, clinical history, surgical details, complications, and outcomes.

RESULT EVALUATION

Primary analysis includes recurrence rate and Kaplan-Meier curves.

Secondary analysis includes complications, pain, quality of life, and reintervention.

LIMITATIONS

No external control group.

ADVERSE EVENTS

Observational study with no additional interventions.

ETHICS

Conducted according to the Declaration of Helsinki and data protection laws.

CONFIDENTIALITY

All personal data anonymized and coded.

INSURANCE

No insurance required due to observational nature.

ECONOMIC REPORT

No funding or compensation.

PRACTICAL CONSIDERATIONS

Data recorded according to Good Clinical Practice.

STATISTICAL ANALYSIS

Descriptive and analytical statistics, including regression and survival analysis.

PUBLICATION

Results will be published in scientific journals.

BIBLIOGRAPHY

(References maintained as in original document)