

# Research on patient satisfaction regarding postoperative analgesia following elective laparoscopic colorectal surgery

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<b>Registration date</b> 30/07/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/07/2025	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study is looking at the best ways to manage pain after keyhole (laparoscopic) bowel surgery. These types of surgeries are part of a modern approach called Enhanced Recovery After Surgery (ERAS), which helps people recover faster and with fewer complications. One important part of this approach is good pain relief, but some common painkillers like opioids (such as morphine) can cause unpleasant side effects like nausea, constipation, and drowsiness. This study will compare three different types of pain relief to see which one works best, helps people recover faster, and improves their quality of life after surgery.

### Who can participate?

Adults over the age of 18 years who are scheduled for planned (elective) keyhole bowel surgery can take part. This includes surgeries like removing part of the rectum or colon. People cannot take part if they are having a different type of surgery (like rectal amputation), if their surgery changes from keyhole to open surgery during the operation, or if they are allergic to the pain medications used in the study.

### What does the study involve?

Participants will receive one of three types of pain relief:

- Epidural analgesia (a type of pain relief given through a small tube in the back)
- Spinal (intrathecal) morphine (a single injection into the spine)
- A combination of painkillers given through a drip (multimodal intravenous analgesia)

People who don't want spinal or epidural pain relief will be placed in the intravenous group. Those who agree to spinal or epidural pain relief will be randomly assigned to one of those two groups. The study will collect information about each participant's health, the type of surgery they had, how long they stayed in hospital, any side effects, and how satisfied they were with their pain relief. Six weeks after surgery, participants will be asked to complete a short questionnaire about their quality of life.

### What are the possible benefits and risks of participating?

There may not be any direct benefit to participants, but the results could help improve pain

relief for future patients having this type of surgery. There are no extra risks involved in taking part, and the usual care and treatment will not be changed.

Where is the study run from?

The study is being carried out at the Clinical Hospital Centre Rijeka in Rijeka, Croatia.

When is the study starting and how long is it expected to run for?

Who is funding the study?

The study is funded by the Clinical Hospital Centre Rijeka, Croatia

Who is the main contact?

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## Contact information

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Nil known

## **Study information**

**Scientific Title**

Patient satisfaction regarding postoperative analgesia following elective laparoscopic colorectal surgery

**Acronym**

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**Study objectives**

Compared to epidural analgesia, intrathecal administration of morphine (in the subarachnoid space) and multimodal intravenous analgesia are associated with faster patient recovery and, consequently, earlier discharge from the hospital, while maintaining an equally good quality of life postoperatively.

**Ethics approval required**

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**Ethics approval(s)**

Approved 11/10/2024, Clinical Hospital Centre Rijeka- Ethics committee (Krešimirova 42, Rijeka, 51000, Croatia; +385 51658808; Kristina.Vucinic@kbc-rijeka.hr), ref: 003-05/24-01/163

**Study design**

Prospective single-center interventional open-label trial

**Primary study design**

Interventional

**Secondary study design**

Randomised parallel trial

**Study setting(s)**

Hospital

**Study type(s)**

Quality of life, Safety, Efficacy

**Participant information sheet**

See study outputs table

## **Health condition(s) or problem(s) studied**

Postoperative analgesia after elective laparoscopic colorectal surgery.

## **Interventions**

This study will observe three patient groups: those with epidural analgesia, those with intrathecally administered morphine, and those with multimodal intravenous analgesia. Patients who refuse one of the forms of neuroaxial analgesia (subarachnoid or epidural analgesia) will be included in the multimodal intravenous analgesia group. Patients who agree to neuroaxial analgesia will be randomized into two groups using the closed envelope method.

Demographic data (age, gender, height, weight, and body mass index), co-morbidities (expressed through ASA status from the preoperative anesthesiological assessment), analgesia modality, type and duration of the surgical procedure, length of hospitalization, postoperative complications/adverse effects, and mortality will be examined.

Patient satisfaction with analgesia will be assessed before discharge from the hospital using a standardized questionnaire (APS-POQ-R - Revised American Pain Society Patient Outcome Questionnaire for Quality Improvement of Pain Management in Hospitalized Adults).

Additionally, six weeks after the surgical procedure, we plan to assess the quality of life of patients using the standardized questionnaire Euro-Qol-5 Dimension (EQ-5D), which is the most commonly used tool for measuring health-related quality of life (HRQoL).

## **Intervention Type**

Procedure/Surgery

## **Primary outcome measure**

Patient satisfaction with analgesia measured using APS-POQ-R—Revised American Pain Society Patient Outcome Questionnaire for Quality Improvement of Pain Management in Hospitalized Adults assessed before discharge from the hospital

## **Secondary outcome measures**

1. Investigate the speed of patient recovery (length of hospital stay), measured in days. Will be assessed using patient medical charts (hospital electronic database)
2. Note potential adverse effects or complications using patient medical charts (hospital electronic database) before hospital discharge
3. Assess the quality of life six weeks after surgery and potentially link the results to the type of analgesia received by the patients, with a special focus on complications and the development of chronic pain. Will be assessed using the standardized questionnaire Euro-Qol-5 Dimension (EQ-5D), obtained via telephone communication with the principal investigator or collaborators six weeks after the surgical procedure

## **Overall study start date**

01/06/2024

## **Completion date**

04/08/2025

## **Eligibility**

### **Key inclusion criteria**

1. Patients scheduled for elective laparoscopic bowel resection due to tumors in the colorectal region

2. All patients must be over the age of 18 years
3. Patients of both genders are eligible
4. Eligible patients must be scheduled for laparoscopic colorectal surgery, including:
  - Anterior resection of the rectum
  - Hemicolectomies

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

90 Years

**Sex**

Both

**Target number of participants**

60

**Total final enrolment**

60

**Key exclusion criteria**

1. Patients who are set to have rectal amputation
2. Those whose surgery changed from laparoscopic to open abdominal surgery
3. Patients who are allergic to the intravenous or local anesthetics and pain relievers outlined in the study

**Date of first enrolment**

15/10/2024

**Date of final enrolment**

05/05/2025

**Locations****Countries of recruitment**

Croatia

**Study participating centre**

Katarina Tomulić Brusich  
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## Sponsor information

### Organisation

Clinical Hospital Centre Rijeka

### Sponsor details

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### Sponsor type

Hospital/treatment centre

### Website

<http://kbc-rijeka.hr>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### Publication and dissemination plan

Planned publication in peer-reviewed journal

### Intention to publish date

01/06/2026

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available upon request from

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## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	in Croatian		29/07/2025	No	Yes