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

Submission date
26/07/2025

Recruitment status
No longer recruiting

Registration date
30/07/2025

Overall study status
Completed

Last Edited
29/07/2025

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Patient satisfaction regarding postoperative analgesia following elective laparoscopic colorectal surgery

Acronym
-

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
Ethics approval required

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

Study type(s)
Quality of life, Safety, Efficacy

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Upper age limit
90 years

Sex
All

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

Funder(s)

Funder type

Other

Funder Name
Investigator initiated and funded

Results and Publications

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?
Participant information sheet	in Croatian		29/07/2025	No	Yes