

Differences in pain relief after open or laparoscopic colorectal cancer surgery with epidural or intravenous medication

Submission date 15/02/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/02/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/03/2025	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

During the years 2013 - 2016 for colonic cancer the standard operating technique in our hospital changed from mainly open to laparoscopic (keyhole surgery) and therefore also the choice of pain relief used during and after the surgery might have changed. We choose to study the period between 2014 and 2016 to evaluate this change in pain treatment and the possible consequences, in addition to changed operating technique, for all patients admitted with this pathology. We tried to answer questions regarding pain treatment, length of stay, complications and 5-year survival.

Who can participate?

All patients scheduled for colonic cancer surgery in an academic tertiary hospital during the years 2014 till 2016.

What does the study involve?

Records were reviewed. The primary outcome of our study was the difference of pain in patients receiving open or laparoscopic interventions with either thoracic epidural (TEA) or intravenous opioid pain (PCIA) relief management. Because it was an observational study there were no benefits or risks for the participants. The study was performed in Maastricht, The Netherlands. Data collection was prospectively recorded in two different data collection systems. Prospective collected data from the Dutch Surgical Colorectal Audit database (DSCA) were combined with prospective collected data from the acute pain service (APS) and the anesthesia registration system. Data analysis started after approval from the medical ethic committee.

What are the possible benefits and risks of participating?

None (retrospective study)

Where is the study run from?

Maastricht University Medical Centre

When is the study starting and how long is it expected to run for?
January 2017 to June 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
P.B.W. Cox, b.cox@mumc.nl

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
METC 17-4-010

Study information

Scientific Title
Thoracic epidural analgesia versus patient-controlled intravenous analgesia for patients undergoing open or laparoscopic colorectal cancer surgery, an observational study

Study objectives
The goal was to evaluate the postoperative analgesic effectiveness of TEA compared to patient controlled intravenous analgesia (PCIA) after open and laparoscopic colorectal surgery, and to verify if the implementation of TEA leads to enhanced recovery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/10/2017, Medical Ethics Committee Maastricht UMC+ (P.Debyelaan 25, postbus 5800, 6202 AZ Maastricht, The Netherlands; +31 433876009; secretariaat.metc@mumc.nl), ref: METC 17-4-010

Study design

Single centre retrospective observational study

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Analgesia approaches for laparoscopic surgery

Interventions

The study was performed in patients scheduled for laparoscopic or open colonic resections with either thoracic epidural (TEA) or intravenous opioid pain (PCIA) relief management. Data collection was prospectively recorded in two different data collection systems. Data from the Dutch Surgical Colorectal Audit database (DSCA) were combined with prospective collected data from the acute pain service (APS) and the anesthesia registration system.

An observational study was performed measuring postoperative pain, LOS, the incidence of epidural side effects, major complications and 5-year survival rate.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Postoperative pain measured using the NRS postoperatively and at day 1, 2 and 3, both at rest and during movement

Key secondary outcome(s)

1. Length of stay (days) measured using patient records
2. Incidence of epidural related side effects measured by clinical observation postoperatively at day 1, 2 and 3
3. Major complications measured using patient records for 30 days after surgery
4. 5-year survival measured using patient records

Completion date

01/06/2020

Eligibility

Key inclusion criteria

All adult patients who underwent colorectal cancer surgery between 2014 and 2016, with ASA status I-IV were included

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

422

Key exclusion criteria

1. No postoperative thoracic epidural analgesia of patient controlled analgesia
2. Double cases
3. Missing data

Date of first enrolment

27/10/2017

Date of final enrolment

01/06/2020

Locations**Countries of recruitment**

Netherlands

Study participating centre

Maastricht University Medical Centre

P. Debyelaan 25

Maastricht

Netherlands

6202 AZ

Sponsor information**Organisation**

Maastricht University Medical Centre

ROR

<https://ror.org/02d9ce178>

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 analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/01/2023	04/03/2025	Yes	No