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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

Registration date
26/02/2021

Overall study status
Completed

Last Edited
04/03/2025

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 Maastrict 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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

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

Secondary outcome measures

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

Overall study start date
17/01/2017

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

Age group
Adult

Sex
Both

Target number of participants
422

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

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.mumc.nl/en

ROR
https://ror.org/02d9ce178

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

Publication and dissemination plan
The aim is to publish this study in the European Journal of Anaesthesiology.

Intention to publish date
01/10/2021

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