

Beneficial effects of thoracic epidural anaesthesia on mortality after surgery for colon cancer

Submission date 25/05/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/06/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/08/2019	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Perioperative use of epidural analgesia reduces the 36-month postoperative mortality rate. This effect may be due to systemic effects of local anaesthetics or to a reduced stress response caused by the thoracic epidural analgesia itself.

Who can participate?

Patients scheduled to undergo elective open colon cancer surgery.

What does the study involve?

Patients records are followed up over a 4 year period following surgery.

What are the possible benefits and risks of participating?

None.

Where is the study run from?

Marienhospital Vechta gGmbH, Germany.

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

January 1997 to December 2015

Who is funding the study?

The study is funded by the investigator.

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

MarienVEC_12

Study information

Scientific Title

Epidural anaesthesia reduces mortality after colon cancer surgery

Acronym

EARMAC

Study objectives

Epidural anaesthesia reduces mortality after colon cancer surgery

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved DATE, Ethikkommission der Ärztekammer Niedersachsen (Ethical Committee of the Ärztekammer Niedersachsen, ÄKN Ethikkommission, Berliner Allee 20, 30175 Hannover, Germany; 05113802208; ethikkommission@aekn.de), ref:

Study design

Observational study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Patients with elective colon cancer surgery

Interventions

Patient records were used to follow-up on outcomes over 4 years for patients who had undergone elective colon cancer surgery with or without thoracic epidural anesthesia/analgesia.

Intervention Type

Other

Primary outcome measure

Mortality, measured by review of patient charts and a database of a local cancer database in Oldenburg, Germany

Secondary outcome measures

1. Perioperative complications
2. Stroke
3. Myocardial infarction
4. Blood transfusion
5. Duration of stay

All measured by review of patient charts and a database of a local cancer database in Oldenburg, Germany

Overall study start date

01/01/2003

Completion date

31/12/2015

Eligibility**Key inclusion criteria**

Scheduled to undergo elective open colon cancer surgery

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

240

Key exclusion criteria

1. Non elective surgery
2. Laparoscopic surgery

Date of first enrolment

01/01/1997

Date of final enrolment

31/12/2007

Locations**Countries of recruitment**

Germany

Study participating centre

Marienhospital Vechta gGmbH

Marienstraße 6-8

Vechta

Germany

49377

Sponsor information**Organisation**

Marienhospital Vechta gGmbH

Sponsor details

Marienstraße 6-8

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christian.hoenemann@kh-vec.de

Sponsor type

Hospital/treatment centre

Website

www.marienhospital-vechta.de

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in BMC Anesthesiology

Intention to publish date

01/06/2019

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