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

Submission date	Recruitment status	[ ] Prospectively registered
25/05/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/06/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/08/2019	Surgery	[ ] 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?
Dr Christian Hönemann,
c.honemann@icloud.com

Contact information

Type(s)

Scientific

Contact name
Dr Christian Hönemann

ORCID ID
https://orcid.org/0000-0002-9658-253X

Contact details
arienstraße 6-8
Vechta
Germany
49377
+4915208961106
christian.hoenemann@kh-vec.de

Additional identifiers

Protocol serial number
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 Aerztekammer Niedersachsen (Ethical Committee of the Aerztekammer Niedersachsen, ÄKN Ethikkommission, Berliner Allee 20, 30175 Hannover, Germany; 05113802208; ethikkommission@aekn.de), ref:

Primary study design
Observational

Study design
Observational study

Study type(s)
Other

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

Key secondary outcome(s)
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

Completion date
31/12/2015

Eligibility

Key inclusion criteria
Scheduled to undergo elective open colon cancer surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
Vechhta
Germany
49377

Sponsor information

Organisation
Marienhospital Vechta gGmbH

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