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The Peri-Operative Epidural Trial pilot study

Submission date 26/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/09/2005	**Overall study status** Completed	
Last Edited 19/06/2009	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.crsu.ca

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00221260

Secondary identifying numbers
MCT-73644

Study information

Scientific Title
Peri-operative epidural in patients with moderate or high risk for cardiorespiratory events who are undergoing non-cardiothoracic surgery: a randomised controlled trial

Acronym
POET

Study objectives
Enrolling patients into the above study is still feasible in the current clinical setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Clinical Research Ethics Board of the University of British Columbia on the 31st March 2005.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Postoperative cardio-respiratory complications

Interventions
Control:
Intraoperative general anesthesia and postoperative intravenous narcotic analgesia.

Intervention:
Intraoperative neuraxial (epidural or spinal) ± general anesthesia and postoperative epidural analgesia.

Trial details received: 12 September 2005

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Rates of enrolment, follow-up, and crossover.

Secondary outcome measures
1. Combined 30-day outcome of all-cause mortality, nonfatal myocardial infarction, cardiac arrest, postoperative pneumonia, and respiratory failure
2. Other clinical outcomes: deep vein thrombosis, pulmonary embolism, transient ischemic attacks, stroke, and congestive heart failure during first 30 post-operative days
3. Safety outcomes: clinically significant bradycardia or hypotension

Overall study start date
01/05/2005

Completion date
30/04/2006

Eligibility

Key inclusion criteria
Any patient undergoing non-cardiopulmonary surgery who:
1. Is greater than or equal to 45 years old, either sex
2. Has an expected length of stay greater than or equal to 48 hours
3. Is undergoing a procedure amenable to postoperative epidural analgesia
4. Fulfils any six criteria for moderate to high cardiorespiratory risk

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
250

Key exclusion criteria
1. Is pregnant or planning to become pregnant before surgery
2. Has a contraindication to epidural analgesia
3. Had a prior adverse reaction to local anesthetics or narcotics
4. Had coronary artery bypass graft surgery with complete revascularisation in the preceding 5

years and has no evidence of cardiac ischemia since the procedure
5. Has pneumonia in the preoperative period
6. Is intubated or mechanically ventilated prior to surgery
7. Has concomitant life-threatening disease likely to limit life expectancy to less than 30 days

Date of first enrolment
01/05/2005

Date of final enrolment
30/04/2006

Locations

Countries of recruitment
Canada

Study participating centre
University of British Columbia
Vancouver
Canada
V5Z 4E3

Sponsor information

Organisation
Vancouver Coastal Health Research Institute, University of British Columbia (Canada)

Sponsor details
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Sponsor type
Not defined

ROR
https://ror.org/03rmrcq20

Funder(s)

Funder type

Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-73644)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/06/2009		Yes	No