

# The Peri-Operative Epidural Trial pilot study

<b>Submission date</b> 26/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/06/2009	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.crsu.ca>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Peter T Choi

### Contact details

University of British Columbia  
Department of Anesthesiology  
Pharmacology & Therapeutics  
910 West 10th Avenue, Room 3200  
Vancouver  
Canada  
V5Z 4E3  
+1 604-875-4111 (68433)  
[petert.choi@vch.ca](mailto:petert.choi@vch.ca)

## 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**

828 West 10th Avenue

Vancouver

Canada

V5Z 1L8

cheryl.davies@vch.ca

**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?
<a href="#">Results article</a>	Results	01/06/2009		Yes	No