ISRCTN18637372 https://doi.org/10.1186/ISRCTN18637372

EPAS: Epidural versus Picra for Abdominal Surgery

Submission date	Recruitment status	[ ] Prospectively registered
19/12/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/12/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/12/2008	Surgery	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
H07-02916

Study information

Scientific Title

Comparison of epidural catheters versus surgical wound catheters for analgesia after major hepatobiliary and pancreatic surgeries

Acronym
EPAS

Study objectives
We hypothesise that surgical wound catheters with patient controlled anaesthesia are equivalent to epidural catheters with patient controlled anaesthesia with respect to post-operative pain, complications and return to function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending as of 19/12/2007 from:
1. University of British Columbia
2. Vancouver Coastal Health

Study design
Randomised, prospective 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
Major hepatobiliary and pancreatic surgeries

Interventions
Epidural catheters and surgical wound catheters.

On the day of surgery, the patient will be randomised to either the epidural or wound catheter. The wound catheter will be placed by the attending surgeon at the end of the procedure, while the epidural will be placed by the anaesthesiologist at the beginning of the procedure. Both groups will also be equipped with patient controlled analgesia (PCA). Our Post-operative Pain Service (POPS) will monitor the pain control of these patients and make adjustments regarding the rate of infusion of both these devices. The removal of the devices will be left at the discretion of the attending anaesthesiologist on POPS, which generally is between 2 - 5 days. The duration of follow up and the intervention will be the length of the patient's inpatient stay, which is obviously individualised for each patient.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
The total amount of analgesic used as determined by the patient controlled anaesthesia pump. This will be assessed via each patient's post-operative anaglesia sheet, which is a common method in our hospital, commonly used by our nursing staff.

Secondary outcome measures
1. The subjective scores of the post-operative pain, monitored via a Visual Analogue Scale (1 - 10) twice daily (BID)
2. Total time requiring the epidural or wound catheter
3. Total length of hospitalisation
4. Level of ambulation and activity, recorded by nursing staff on analgesic sheets
5. Time for return of full diet, recorded by nursing staff on analgesic sheets
6. Time for return of full gastrointestinal function, recorded by nursing staff on analgesic sheets

Overall study start date
01/02/2008

Completion date
01/02/2008

Eligibility

Key inclusion criteria
Patients will be eligible to be enrolled in the study only after each of the following criteria are met:
1. Aged greater than or equal to 18 years, either sex
2. Cheyne abdominal incision used
3. Pre-operative International Normalised Ratio (INR) less than or equal to 1.3
4. Pre-operative platelet count greater than or equal to 100,000/uL
5. No prior epigastric incision
6. Body mass index (BMI) less than 30 kg/m^2
7. No signs of systemic sepsis
8. No allergies to agents or medications
9. Willingness to accept either surgical wound catheter or epidural catheters

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/02/2008

Date of final enrolment
01/02/2008

Locations

Countries of recruitment
Canada

Study participating centre
Gordon & Leslie Diamond Health Care Center
Vancouver
Canada
V5Z 1M9

Sponsor information

Organisation
University of British Columbia (Canada)

Sponsor details
Department of Surgery
Faculty of Medicine
3100, 910 West 10th Avenue
Vancouver
Canada
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Sponsor type
University/education

Website
http://www.ubc.ca/

ROR
https://ror.org/03rmrcq20

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Canada) - no external funding will be sought

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