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Comparison of epidural catheters and wound catheters for pain control after liver surgery

Submission date
03/02/2015

Recruitment status
No longer recruiting

Registration date
13/04/2015

Overall study status
Completed

Last Edited
18/12/2018

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
At St James's University Hospital, the standard practice for analgesia (pain relief) after abdominal surgery is to use epidural catheters, which involves injecting anaesthetic through a catheter (tube) into a space inside the spine. The aim of this study is to compare this well known technique with wound catheters plus patient-controlled analgesia (PCA), where the patient administers their own pain relief.

Who can participate?
Adults scheduled to have liver surgery

What does the study involve?
Patients are randomly allocated to one of two treatments: wound catheters for continuous infusion of local anaesthetic and PCA with opioids, or epidural catheters (standard of care). The care received after surgery is exactly the same with the exception of pain control in the initial 72 hours after surgery. Length of stay is measured from surgery to becoming medically fit for discharge.

What are the possible benefits and risks of participating?
A potential benefit is shorter recovery. Risks are related to the insertion of the wound catheters only.

Where is the study run from?
St James's University Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2015 to December 2017

Who is funding the study?
Investigator initiated and funded (UK)

Who is the main contact?
Mr Ernest Hidalgo
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RL14/11048

Study information

Scientific Title
Comparison of epidural analgesia and patient-controlled continuous local anaesthetic infusion via a wound catheter for pain control after open liver resection: an open-label randomised controlled trial

Study objectives
1. Pain relieve with continuous preoperative infusion of local anaesthetic via wound catheters will minimise the use of patient-controlled analgesia (PCA) with intravenous opioids and will be

similar to epidural analgesia.
2. Without epidural analgesia, recovery following surgery will be optimised with a shorter postoperative stay.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee Yorkshire and Humber - Bradford Leeds, 05/12/2014, ref: 14/YH/1267

Study design
Open-label randomised control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Postoperative pain control and recovery after surgery

Interventions
1. Wound catheters for continuous infusion of local anaesthesia, along with intravenous PCA with morphine
2. Epidural catheters (standard of care)

Intervention Type
Procedure/Surgery

Primary outcome measure
Length of stay from surgery to becoming medically fit for discharge, measured in days

Secondary outcome measures
1. Time in theatre:
1.1. Anaesthetic time (anaesthetic room to incision)
1.2. Surgical time (incision to completion of closure, including the insertion of wound catheters)
2. Pain scores, estimated with Painmatcher® in addition to visual analogue scale everyday until discharge
3. Length of stay in high dependency unit (days)

4. Peak flow measurements at baseline and day 1 to day 5
5. Total volume (mL) of intravenous fluid required in theatre and every 24 hours
6. Total need for vasopressors
7. Total daily opioid analgesia (conversion to morphine mg equivalent) required everyday until discharge
8. Time to first bowel movement (days)
9. Nausea, on a scale of 1–3 on days 1, 2 and 3
10. Sedation, on a scale of 1–3 on days 1, 2 and 3
11. Mobility: time to first sitting in chair (hours)
12. Incidence of complications (related to surgery and analgesia), up to discharge
13. Patient satisfaction (EQ-5D questionnaire)

Overall study start date
01/04/2015

Completion date
01/12/2017

Eligibility

Key inclusion criteria
1. Age >18 years old
2. Scheduled to undergo an open liver resection

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80 (powered to 80% with p<0.05): 40 per arm

Key exclusion criteria
1. Contraindications to epidural
2. Inability to consent
3. Age < 18 years old
4. Liver resection combined with a second procedure
5. Pregnancy
6. Lactation
7. History of chronic pain
8. Body-mass index <18 kg/m2 or >40 kg/m2

Date of first enrolment

15/03/2015

Date of final enrolment
01/10/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St James's University Hospital
Bexley Wing
3rd Floor
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust

Sponsor details
34 Hyde Terrace
Leeds
England
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
1. The study will be audited at 6 months and 12 months after it starts; a data reviewing committee will be established to oversee the results
2. Following termination of recruitment and data analysis, the aim is to produce a manuscript for publication as well as in-house and appropriate conference presentations

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Ernest Hidalgo (ernest.hidalgo@nhs.net).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		18/12/2018	18/12/2018	No	No
HRA research summary			28/06/2023	No	No