

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

Submission date 03/02/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/04/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/12/2018	Condition category Surgery	<input type="checkbox"/> 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

Protocol serial number

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)

Study design

Open-label randomised control trial

Primary study design

Interventional

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

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

ROR

<https://ror.org/00v4dac24>

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/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	Participant information sheet	18/12/2018	18/12/2018	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes