

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

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

## Contact information

### Type(s)

Public

### Contact name

Mr Ernest Hidalgo

### ORCID ID

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### Contact details

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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/m<sup>2</sup> or >40 kg/m<sup>2</sup>

**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

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# 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](mailto:ernest.hidalgo@nhs.net)).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>		18/12/2018	18/12/2018	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No