

HEpatic Resection Analgesia and Length of time to Discharge

Submission date 28/01/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 22/04/2021	Condition category Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
17760

Study information

Scientific Title

Short-term outcomes with intrathecal opioid and patient controlled analgesia versus thoracic epidural analgesia for hepatic resection: a randomised controlled trial

Acronym

HERALD1

Study objectives

Hepatic resection is an operation where the part of the liver containing cancer is removed. Pain relief plays an important part in the patient's recovery following this type of surgery, with the potential to improve patient outcomes. This study will provide high-quality evidence as to whether the choice of pain relief affects the length of time that patients take to recover from hepatic resection surgery. Showing the use of either spinal or epidural analgesia to be associated with better outcomes including time until medically fit for discharge will ensure that the most effective form of analgesia is used for this surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC approval date 09/10/2014, ref: 14/LO/1174

Study design

Randomised; Interventional; Design type: Treatment

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hepatic resection

Interventions

Patients will be randomised to either thoracic epidural analgesia or intrathecal diamorphine with Fentanyl PCA.

Intervention Type

Drug

Phase

Not Applicable

Primary outcome(s)

Length of stay until medically fit for discharge; Timepoint(s): Time until medically fit for discharge post operatively

Key secondary outcome(s)

N/A

Completion date

01/01/2020

Eligibility

Key inclusion criteria

1. Consent for enrolment
2. Patients presenting for elective one-stage open Hepatic Resection surgery at the Royal Free Hospital, London
3. Patients receiving a midline +/- a transverse incision in the right upper quadrant ('reverse L incision')
4. No contraindication to, or refusal to receive, central neuraxial block (epidural or spinal analgesia)
5. Aged at least 16

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

98

Key exclusion criteria

1. Adult unable to give informed consent
2. Allergy to local anaesthetics
3. Infection around the potential puncture site
4. Coagulation disorders (INR >1.5, platelets <100 x 10⁹)
5. Chronic pain, requiring opioid analgesia or illicit opioid use
6. Mobility problems requiring assistance

Date of first enrolment

01/12/2014

Date of final enrolment

01/10/2019

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
University College London

ROR
<https://ror.org/02jx3x895>

Funder(s)

Funder type
Government

Funder Name
National Institute of Academic Anaesthesia

Alternative Name(s)
NIAA

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Funder Name
Royal Free Charity (UK)

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes