HEpatic Resection Analgesia and Length of time to Discharge

Submission date	Recruitment status No longer recruiting	Prospectively registered		
28/01/2015		Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/01/2015 Last Edited	Completed Condition category	☐ Results		
		Individual participant data		
22/04/2021	Surgery	Record updated in last year		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Ben Clevenger

ORCID ID

http://orcid.org/0000-0001-5659-6323

Contact details

Department of Anaesthesia Royal Free Hospital Pond Street London United Kingdom NW3 2QG +44 (0)20 7794 0500 Ext: 24534 b.clevenger@nhs.net

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

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

Secondary outcome measures

N/A

Overall study start date

01/12/2014

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

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 98; UK Sample Size: 98

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 10(9))
- 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

England

United Kingdom

Study participating centre

Royal Free Hospital

Pond Street London United Kingdom NW3 2QG

Sponsor information

Organisation

University College London

Sponsor details

Gower Street London England United Kingdom WC1E 6BT

Sponsor type

University/education

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

Publication and dissemination plan

Planned publication in a high impact peer-reviewed journal.

Intention to publish date

01/08/2021

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