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HEpatic Resection Analgesia and Length of time to Discharge

Submission date	Recruitment status	[ ] Prospectively registered
28/01/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/01/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] 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

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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

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment

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 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
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