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HEpatic Resection Analgesia and Length of time to Discharge

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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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