

Prevention of shoulder tip pain after right hemihepatectomy

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/12/2014	Condition category Signs and Symptoms	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0025128440

Study information

Scientific Title

Prevention of shoulder tip pain after right hemihepatectomy

Study objectives

To assess whether infiltration of the diaphragm with local anaesthetic will prevent shoulder tip pain after hemihepatectomy

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Signs and Symptoms: Post-operative pain

Interventions

At end of proposed surgery prior to closure of abdomen, the diaphragm will be infiltrated with 20 ml of solution consisting of either 0.25% bupivacaine or 0.9% saline by the surgeon. Solutions will be made up in Pharmacy and delivered in sterile syringes such that neither surgeon nor anaesthetist will know what has been administered. Closure of abdomen and recovery from anaesthesia will proceed in normal way and patient will be moved to recovery area. When recovered they will be assessed for presence/absence of shoulder-tip and/or abdominal pain. (If abdominal pain is present, epidural will be topped up in usual manner). If shoulder-tip pain is present attempts will be made to rate this as mild, moderate or severe. Rescue analgesia will be with ketorolac as is current practice.

Intervention Type

Procedure/Surgery

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/2003

Completion date

01/02/2006

Eligibility

Key inclusion criteria

40 adult patients

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

40

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/2003

Date of final enrolment

01/02/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University Hospital Aintree
Liverpool
United Kingdom
L9 7AL

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Aintree Hospitals NHS Trust (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration