ISRCTN29748753 https://doi.org/10.1186/ISRCTN29748753

Periportal Bupivacaine For Pain Relief After Laparoscopic Cholecysectomy

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 08/04/2014	**Condition category** Signs and Symptoms	

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
N0650147577

Study information

Scientific Title

Study objectives
1. Does Pre-incisional injection of bupivacaine decrease postoperative pain following laparoscopic cholecystectomy and allow for early discharge from hospital?
2. To determine any early or late (6 week) related complications.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Post operative pain

Interventions
Randomisation of patients to intervention group and control group.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Pain intensity scored using visual analogue scale at 4, 6 and 24 hrs from the commencement of operation
2. Time to first demand of analgesia
3. Total analgesic requirement in first 24 hrs

4. Assessment of opportunity for same day discharge
5. Assessment of early/late (6 weeks) postoperative complications
6. Scar quality at 6 weeks

Secondary outcome measures
Not provided at time of registration

Overall study start date
17/01/2002

Completion date
31/12/2006

Eligibility

Key inclusion criteria
60 patients from waiting lists of two General Surgeons based at Ormskirk District General Hospital (RJL Anderson; NK Matar)

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
17/01/2002

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Surgical CSG
Ormskirk
United Kingdom
L39 2AZ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Southport and Ormskirk Hospital 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