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Periportal Bupivacaine For Pain Relief After Laparoscopic Cholecysectomy

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr R Anderson

Contact details
Surgical CSG
Ormskirk Dist Gen Hosp
Wigan Road
Ormskirk
United Kingdom
L39 2AZ

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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(s)
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

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Surgical CSG
Ormskirk
United Kingdom
L39 2AZ

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Southport and Ormskirk Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration