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Intraperitoneal levobupivacaine and dexamethasone for post-operative pain after laparoscopic cholecystectomy

Submission date 30/09/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Stopped	
Last Edited 18/11/2016	**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
N0280156550

Study information

Scientific Title
Intraperitoneal levobupivacaine and dexamethasone for post-operative pain after laparoscopic cholecystectomy

Study objectives
Intraperitoneal levobupivacaine and dexamethasone for Post-operative pain after laparoscopic cholecystectomy

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
Randomised Controlled Trial. 3 groups:
1. Control group will not receive intraperitoneal local anaesthetic or dexamethasone as is our usual practice
2. L group will receive 15 ml of 0,5% levobupivacaine after establishing pneumoperitoneum and again at the end of the procedure
3. LD group as group L plus dexamethasone

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Pain Scores

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2004

Completion date
01/07/2006

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Patients undergoing Laparoscopic Cholecystectomy

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
90 patients, 30 in each group

Key exclusion criteria
1. Patients allergic to local anaesthetics or dexamethasone, ASA IV and V patients.
2. Patients with acute cholecystitis
3. Patients with previous laparotomy, any intraoperative complications like perforation of the gall bladder, major vascular injury and any procedure which is converted to an open one

Date of first enrolment
01/10/2004

Date of final enrolment
01/07/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Anaesthetic Department Arrowe Park Hospital
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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
Wirral Hospitals NHS Trust (UK) - NHS R&D Support Funding

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