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

Submission date 30/09/2005	Recruitment status Stopped	Prospectively registered
		[_] Protocol
Registration date	Overall study status	[] Statistical analysis plan
30/09/2005	Stopped	[_] Results
Last Edited 18/11/2016	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

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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 Wirral United Kingdom CH49 5PE

Sponsor information

Organisation Department of Health

Sponsor details Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

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