ISRCTN68753145 https://doi.org/10.1186/ISRCTN68753145

Prospective randomized trial to assess the efficacy of 0.5% Marcaine subserosal injection in the gall bladder fossa to reduce the post operative pain from laparoscopic cholecystectomy

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 29/09/2006	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 06/09/2016	**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

Protocol serial number
N0008171900

Study information

Scientific Title
Prospective randomized trial to assess the efficacy of 0.5% Marcaine subserosal injection in the gall bladder fossa to reduce the post operative pain from laparoscopic cholecystectomy

Study objectives
Pain after Laparoscopic Cholecystectomy (key hole removal of gall bladder) is much lower than an open operation for the removal of gall bladder. However one can still expect mild to moderate pain after the key hole operation.
Can we reduce the post operative pain after the key hole operation by injecting local anaesthetic in the gall bladder bed?

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Signs and Symptoms: Pain

Interventions
We will recruit every suitable patient who undergoes a Laparoscopic Cholecystectomy under either of the Upper Gastrointestinal Surgeons at Frimley Park Hospital.
They will be given information leaflet about Laparoscopic cholecystectomy, and also given a leaflet with a diagram showing the site of injection.
An informed consent will be taken for the study in addition to the standard consent form for the procedure.
The surgeon will be unaware of the nature of the solution that he will inject into the gall bladder fossa (saline and bupivicaine injection will be shown to him pre op to check their details).
A member of the team will draw an envelope to randomize the patients in either arm and will brief the nurse about the injection without the surgeon becoming aware of this Solution will be carefully injected with a 0.2 mm epidural needle connected to a syringe percutaneously in the subserosal area taking great care not to inject intravascularly.
The rest of the operation will be performed as normal.

Pain levels will be assessed at various periods after the operation and the results will be compared.

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Marcaine

Primary outcome(s)
Post operative pain scores

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

Completion date
01/01/2006

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/08/2005

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Portsmouth Road
Camberley
United Kingdom
GU16 7UJ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
Frimley Park Hospital NHS Foundation Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration