

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/09/2016	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 bupivacaine 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)

Marcaïne

Primary outcome measure

Post operative pain scores

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/08/2005

Completion date

01/01/2006

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

We plan to recruit approximately 25 patients in each arm

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

England

United Kingdom

Study participating centre

Portsmouth Road

Camberley

United Kingdom

GU16 7UJ

Sponsor information

Organisation

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

Sponsor details

The Department of Health

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Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Frimley Park Hospital NHS Foundation 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