

# 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

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| <b>Submission date</b><br>29/09/2006   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>29/09/2006 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>06/09/2016       | <b>Condition category</b><br>Signs and Symptoms   | <input type="checkbox"/> Individual participant data<br><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

**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 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)**

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  
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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

### Study outputs

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |