

Post-Laparoscopic Cholecystectomy Pain: Benefit of Intraperitoneal Saline

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 09/09/2016	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
N0533152392

Study information

Scientific Title

Post-Laparoscopic Cholecystectomy Pain: Benefit of Intraperitoneal Saline

Study objectives

Study aims:

1. To assess a simple way of pain reduction post-operatively
2. To evaluate if this intervention influences the timing of patient discharge and the rate of day case Laparoscopic Cholecystectomy
3. To examine individual differences and identify patient characteristics that may predict likely success and failure from this intervention

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)

Not specified

Study type(s)

Not Specified

Participant information sheet**Health condition(s) or problem(s) studied**

Signs and Symptoms: Post operative pain

Interventions

1. Normal saline instilled intraperitoneally at end of operation
2. Control

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Pain Score
2. Nausea

3. Vomiting
4. Duration of hospitalisation
5. Re-admission within 10 days

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/2004

Completion date

30/09/2005

Eligibility

Key inclusion criteria

80 patients at Queen Mary's

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

80

Key exclusion criteria

1. Any procedure which had to be converted to laparotomy
2. Any patient where the operating surgeon did not adhere to the study protocol
3. Any patient whose cognitive function does not allow them to understand consent to this study

Date of first enrolment

01/10/2004

Date of final enrolment

30/09/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Queen Mary's Sidcup NHS Trust
Sidcup
United Kingdom
DA14 6LT

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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SW1A 2NL
+44 (0)20 7307 2622
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Queen Mary's Sidcup NHS 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