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Post-Laparoscopic Cholecystectomy Pain: Benefit of Intraperitoneal Saline

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 09/09/2016	**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

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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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