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Laparoscopic cholecystectomy: 5-mm versus 3-mm ports

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/07/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/09/2013	Digestive System	

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
lapchole3mm

Study information

Scientific Title
A prospective, randomised, double-blind trial comparing 5-mm versus 3-mm ports for laparoscopic cholecystectomy

Study objectives
The principal research question is to see if there is any benefit in terms of post-operative pain and cosmetic outcome following laparoscopic cholecystectomy when the ports are reduced in size from 5-mm to 3-mm whilst evaluating the 5-mm technique for patient satisfaction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submitted to Cambridgeshire 4 Research Ethics Committee (REC) on the 5th October 2009, review taking place on the 22nd October 2009 (ref: 09/H0305/96)

Study design
Interventional single centre double blind 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Symptomatic gallstone disease including pancreatitis

Interventions
Patients will be randomised to the standard '5-mm' laparoscopic cholecystectomy or the '3-mm' laparoscopic cholecystectomy. The difference between the two being the epigastric and right upper quadrant ports. The umbilical port is 10-mm in size in both cases.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Post-operative pain, measured with the Visual Analogue Scale at 6 hours, 1 week and 6 months post-operatively
2. Scar cosmesis, assessed at 6 months using a validated scar questionnaire - Patient Scar Assessment Questionnaire

Secondary outcome measures
1. Operating time, measured in minutes and starting from the time the surgeon is ready to make the first incision until the time the dressings have been applied
2. Conversion to the other technique will apply in the 3-mm group only and the use of any 5-mm port to aid removal of the gallbladder will be classed as a conversion to the standard technique. Any conversions to open will also be recorded
3. Histology of the gallbladders, assessed from the formal histology reports and will be divided into acute cholecystitis, chronic cholecystitis, and normal gallbladder wall
4. Gallbladder wall thickness
5. Operative complications, measured immediately, and late complications will be assessed at 1 week and at 6-month follow up appointments

Overall study start date
01/12/2009

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Symptomatic gallstone disease
2. Age 18 to 70 years, either sex
3. Suitable for day-case procedure

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
100

Key exclusion criteria

1. Acute cholecystitis or empyema of gallbladder
2. Not fit for day-case procedure

Date of first enrolment
01/12/2009

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
c/o Mr Rhodes Secretary
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
Norfolk and Norwich University Hospitals NHS Foundation Trust (UK)

Sponsor details
c/o Kath Andrews
Research and Development Office
Level 3 East Block, Colney Lane
Norwich
England
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Sponsor type
Hospital/treatment centre

Website
http://www.nnuh.nhs.uk/

ROR
https://ror.org/01wspv808

Funder(s)

Funder type
Other

Funder Name
Karl Storz (UK) - providing equipment

Funder Name
All other costs will be covered by NHS under usual treatment costs.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2013		Yes	No