Laparoscopic cholecystectomy: 5-mm versus 3-mm ports

Submission date	Recruitment status No longer recruiting	Prospectively registered	
30/09/2009		☐ 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

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

- 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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

All

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

United Kingdom

England

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)

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

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

Participant information sheet 11/11/2025 No Yes