

# Laparoscopic cholecystectomy: 5-mm versus 3-mm ports

<b>Submission date</b> 30/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 21/07/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/09/2013	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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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?
<a href="#">Results article</a>	results	01/10/2013		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes