

# 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

**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

United Kingdom

NR4 7UY

**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?
<a href="#">Results article</a>	results	01/10/2013		Yes	No