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Traditional laparoscopic cholecystectomy versus SILS™ port laparoscopic cholecystectomy

Submission date 13/01/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/02/2009	**Overall study status** Completed	
Last Edited 21/05/2013	**Condition category** Surgery	

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
NCT00832767

Secondary identifying numbers
AS08012

Study information

Scientific Title
Prospective randomised controlled trial of traditional laparoscopic cholecystectomy versus SILS™ port laparoscopic cholecystectomy

Acronym
SILS™ Port Laparoscopic Cholecystectomy Study

Study objectives
The objectives of this trial are: 1) to assess the feasibility and safety of performing SILS™ port cholecystectomy, and 2) to monitor and compare the outcomes of SILS™ port cholecystectomy versus 4PLC to objectively document the scientific merit, and the perceived advantages of SILS™ port cholecystectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Italy: Ethics Committee, Universita Cattolica del Sacro Cuore, approved on 02/12/2008 (ref: Prot. cm.P822 [A.1505]/C.E./2008)
UK: To be submitted to Ethics Committee, Imperial College London, St Mary's Hospital, in January 2009.
USA: University Hospital Case Medical Center, Institutional Review Board for Human Investigations. Approval pending as of 13/01/2009.

Study design
Randomised controlled single-blind multi-centre study

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
Acute calculus, acalculous cholecystitis

Interventions
Traditional laparoscopic cholecystectomy versus SILS™ port laparoscopic cholecystectomy

Intervention Type

Procedure/Surgery

Phase
Phase IV

Primary outcome measure
1. Feasibility and safety of SILS™ port cholecystectomy versus four-port traditional laparoscopic cholecystectomy as indicated by intraoperative and postoperative adverse events up to one year
2. Operative time
3. Blood loss

Secondary outcome measures
1. Pain, assessed by the Pain Intensity numerical rating scale at 8 different timepoints within the first month post surgery
2. Cosmesis, assessed at 5 different timepoints between 1 week and 1 year post surgery by the following:
2.1. Modified Hollander scale
2.2. Body image questionnaire
2.3. Photo series questionnaire
3. Quality of life, assessed by the SF-8® and SF-12® Health Survey questionnaires at 7 different timepoints, once prior to surgery and 6 times up to 1 month post surgery
4. Time to return to normal activity
5. Time required for insertion of SILS™ Port compared to 4 standard ports

Overall study start date
03/02/2009

Completion date
01/02/2011

Eligibility

Key inclusion criteria
1. Both males and females, between 18 and 65 years old
2. The patient has a diagnosis of biliary colic with documented gallstones or polyps by imaging or biliary dyskinesia with documented ejection fraction (EF) <30%
3. Body mass index (BMI) <35 kg/m^2
4. The patient or patient's legal representative has been informed of the nature of the study, agrees to its provisions, and has provided written informed consent as approved by the Institutional Review Board/Ethics Committee (IRB/EC) of the respective clinical site
5. The patient agrees to return to the same research facility for all study-required post-procedure follow-up visits

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Any female patient who is pregnant, suspected pregnant, or nursing
2. Any patient with acute calculus or acalculous cholecystitis
3. Any patient who has had an upper midline or right sub costal incision
4. Any patient with pre-operative indication for a cholangiogram
5. Any patient with American Society of Anesthesiologists (ASA) >3 with normal liver function
6. Any patient who is undergoing peritoneal dialysis (PD)
7. Any patient who has an unrepaired umbilical hernia or has had prior umbilical hernia repair

Date of first enrolment
03/02/2009

Date of final enrolment
01/02/2011

Locations

Countries of recruitment
Italy

United Kingdom

United States of America

Study participating centre
11100 Euclid Avenue
Cleveland
United States of America
44106

Sponsor information

Organisation
Covidien Surgical Devices (USA)

Sponsor details

c/o Donna Biracree
60 Middletown Avenue
North Haven
United States of America
06473

Sponsor type
Industry

Website
http://www.covidien.com

ROR
https://ror.org/00grd1h17

Funder(s)

Funder type
Industry

Funder Name
Covidien Surgical Devices (USA)

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	01/06/2013		Yes	No