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Single-center experience of needle-scopic grasper assisted single incision laparoscopic cholecystectomy for gallbladder benign disease: comparison with conventional 3-port laparoscopic cholecystectomy

Submission date
30/10/2015

Recruitment status
No longer recruiting

Registration date
18/11/2015

Overall study status
Completed

Last Edited
17/11/2015

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The gallbladder is a pear-shaped pouch for storing bile, a liquid made by the liver to help digest fatty foods. Laparoscopic cholecystectomy is an operation to remove the gallbladder and is the standard treatment for benign gallbladder diseases. Laparoscopic surgery leaves several scars after the operation. Operations with fewer incisions have been attempted, including single-incision laparoscopic surgery (SILS). SILS is cosmetically acceptable but is technically difficult and demanding. Therefore, we are intended to overcome the difficulties of SILS by adding an incision for an instrument called a needlescopic grasper, which just leaves a negligible scar after the operation. The aim of this study is to evaluate the safety and feasibility of needlescopic grasper assisted SILC (nSILC) compared with conventional laparoscopic cholecystectomy (CLC).

Who can participate?
Patients undergoing laparoscopic cholecystectomy for benign gallbladder disease.

What does the study involve?
We review the medical records of patients who underwent CLC or nSILC to investigate the difference in surgical outcomes, in particular to see if there are any differences in the operation time, and pain and complications following the operation.

Where is the study run from?
Uijeongbu St. Mary's Hospital (South Korea)

When is the study starting and how long is it expected to run for?
October 2011 to December 2012

Who is funding the study?
This study performed without funding and all members of this study have no competing interests

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BSUR-D-15-00094R1

Study information

Scientific Title
Single-center experience of needle-scopic grasper assisted single incision laparoscopic cholecystectomy for gallbladder benign disease: comparison with conventional 3-port laparoscopic cholecystectomy

Study objectives
Single incision laparoscopic cholecystectomy (SILC) has some technical problems. Our group has performed needlescopic grasper assisted SILC (nSILC) to overcome these problems. In this study, we introduce our technique and evaluate the safety and feasibility of this technique comparing with the conventional laparoscopic cholecystectomy (CLC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Uijeongbu St. Mary's Hospital Institutional Review Board, 22/01/2015, Study No. UC15RISI0004

Study design
Retrospective case-control study

Primary study design
Observational

Secondary study design
Case-control study

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
Patients with a benign gallbladder disease prompting operative intervention

Interventions
The medical records of 485 patients who received nSILC and CLC were reviewed retrospectively. Surgical outcomes including operative time, hospital stay, postoperative pain and perioperative complication were compared between the two techniques.

Intervention Type
Procedure/Surgery

Primary outcome measure
Overall operative time

Secondary outcome measures
1. Time taken to locate the critical view of safety (CVS) during operation
2. The incidence of conversion operation
3. Postoperative pain measured using the visual analogue scale (VAS)
4. Incidences of postoperative complications

Outcomes measured at baseline (immediately after admission), operation, postoperative periods of admission (postoperative day 1 and 2, and the day of discharge), and the time when patients visited the outpatient clinic after discharge.

Overall study start date
14/10/2011

Completion date

31/12/2012

Eligibility

Key inclusion criteria
Patients who underwent laparoscopic cholecystectomy for acute and chronic cholecystitis at a single institution

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
485

Key exclusion criteria
1. Acute cholecystitis
2. Obese patients
3. History of previous abdominal surgery

Date of first enrolment
14/10/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Korea, South

Study participating centre
Uijeongbu St Mary's Hospital
College of Medicine
The Catholic University of Korea
Uijeongbu
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Sponsor information

Organisation
Uijeongbu St Mary's Hospital (South Korea)

Sponsor details
The Catholic University of Korea
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02ezaf703

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request