

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/11/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/11/2015	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Korea, South

480-717

Sponsor information

Organisation

Uijeongbu St Mary's Hospital (South Korea)

Sponsor details

The Catholic University of Korea

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Uijeongbu

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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