

# Laparo- Endoscopic Single site Surgery vs Conventional Laparoscopic Removal of the Gall Bladder

Published: 27-09-2010

Last updated: 03-05-2024

Main objective research Investigate whether a significant difference exists in pain (VAS score) between the conventional laparoscopic approach and the approach for a gallbladder removal  
LESS Secondary goals a. Explore the possibility of a significant...

|                              |                                      |
|------------------------------|--------------------------------------|
| <b>Ethical review</b>        | Approved WMO                         |
| <b>Status</b>                | Pending                              |
| <b>Health condition type</b> | Hepatobiliary therapeutic procedures |
| <b>Study type</b>            | Interventional                       |

## Summary

### ID

NL-OMON34133

### Source

ToetsingOnline

### Brief title

GALLESS study

### Condition

- Hepatobiliary therapeutic procedures

### Synonym

Gallbladder removal, Symptomatic Gallstones

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Alysis Zorggroep

**Source(s) of monetary or material Support:** Eigen onderzoeksfonds chirurgie

## Intervention

**Keyword:** Galbladder Removal, LESS, Single Site Surgery

## Outcome measures

### Primary outcome

Main objective research

Investigate whether a significant difference in pain (VAS score) between the conventional laparoscopic approach and the approach for a gallbladder removal LESS

Either VAS scores

### Secondary outcome

Secondary goals

- a. Explore the possibility of a significant difference in abdominal and umbilical rupture between the different approaches
- b. Investigate whether a significant difference in wound infection between the different approaches.
- c. Investigate whether a difference in patient satisfaction as to the final outcome between the different approaches.
- d. Investigate whether there is a difference in overall complications between the different approaches
- e. Investigate whether there is a difference in operative time
- f. Investigate whether there is a difference in treatment costs

## Study description

### Background summary

The laparoscopic cholecystectomy led to a surgical revolution in the early 90s. The minimal invasive technique resulted in less pain, less hospitalization and better cosmetic result. After a fast implementation, the technique is now standardized, with 3 to 4 trochars and use of the \*critical view of safety\* [1,2].

Since the publications of Kalloo and Rao in 2004 about NOTES; operating through natural orifices a second revolution seemed to present itself. Technical restrictions and closer scrutiny in comparison with 20 years ago no breakthrough of NOTES was seen. There is renewed interest for refinement of minimally invasive technique. Operating through a single incision through the umbilicus is one example. The umbilicus is not a "natural orifice", but a scar and naturally lends itself to cosmetic and practical reasons as well access to the abdomen [3-6].

Applying a single approach to transumbilical laparoscopy is not new, but has rather little followers [7-9]. Recently, a number of ports have come available that make use of this technique (Single Incision Laparoscopic Surgery-port (SILS) or Laparo-Endoscopic Single Site Surgery (LESS) [8, 10-16].

In 2007, our clinic performed the first hybrid NOTES transvaginal cholecystectomy with good results. On April 21, 2009 the first laparoscopic cholecystectomy was performed using the SILS \* port and we have since performed fifteen procedures.

All procedures were successfully completed without conversion or additional incisions. In all cases, the Critical View of Safety was achieved. The average was operating time was 43 (31-51) minutes. Blood loss was in all cases close to zero.

All patients felt well after surgery and gave an average VAS pain score of 4.5 (2-6) by use of paracetamol and diclofenac the morning after surgery. The pain was in all cases at the site of the incision. Day after surgery all patients were discharged in good condition. There were no readmissions. A check two weeks postoperative revealed one patient with a small wound abscess. After incision this infection completely healed. In addition, one patient developed a hypertrophic scar is. Nevertheless, all patients were satisfied with the cosmetic result. All were pain free after the fifth postoperative day.

This new approach seems a step towards less invasive surgery and seems promising. However, there remain a number of questions that must be answered before this technique can be used by default. The technique can not directly be used by anyone, because it requires some training through the small space which needs to be worked. Also, the amount of pain experienced postoperatively might

be greater. Because the LESS technique uses the umbilicus there is theoretically a higher risk of infection of the umbilicus if not properly disinfected. In addition, the incision is about an inch longer than the usual incision just below the umbilicus. It is therefore possible that an umbilical rupture occurs faster. In this randomized study, we further explore these potential drawbacks.

## **Study objective**

Main objective research

Investigate whether a significant difference exists in pain (VAS score) between the conventional laparoscopic approach and the approach for a gallbladder removal LESS

Secondary goals

- a. Explore the possibility of a significant difference in abdominal and umbilical rupture between the different approaches
- b. Investigate whether a significant difference in wound infection between the different approaches.
- c. Investigate whether a difference in patient satisfaction as to the final outcome between the different approaches.
- d. Investigate whether there is a difference in overall complications between the different approaches
- e. Investigate whether there is a difference in operative time
- f. Investigate whether there is a difference in treatment costs

## **Study design**

In our clinic on an annual basis approximately 300 gall bladders are removed. Such removals are always up first approached laparoscopically. Only with anatomical problems or serious complications these are sometimes converted to an open procedure.

The time between operation and being put on the waiting list is currently 3 months. After patients are seen by the surgeon for symptomatic gallstones a standard blood test and a standard ultrasound is performed. At this moment, the patient is informed of the possibility for participation in this investigation and the patient gets additional information to take home. After two weeks the patient is called back by the attending surgeon and in case of a positive response, patients are invited for an informative conversation, and remaining questions can be asked. If the patient wants to participate, an Informed Consent (IC) will be signed.

Once these patients are included, patients were randomized using the envelope method. The patient knows a few months before the operation which approach it will get. The waiting time is the same for both interventions and participation in this study will not delay care

The operations themselves are performed as described under the heading

"different approaches".

Postoperatively we will use the regular police checks. Patients are seen by the principal investigator and the attending surgeon. During these visits, the patient weighed and the medication inventory. All data is recorded on the CRF. The follow-up visits can be found in the attached survey plan. During the 1 and 6 monthly checks will the incisions be investigated and judged whether or not infection. In addition, patients are prompted complaints. During the 6 monthly check is in addition to all the patients were asked how satisfied they are with the outcome on a scale of 1 to 10 and is investigated with an ultrasound or abdominal wall fractures.

PreOK Na operatie 1 Week TC 1

Maand 3 Maand

Length X X X

Weight X X X

History X

Echo abdomen X X

Laboratory X

Complaints X X X X

VAS score X X

X X X

## **Intervention**

The conventional technique

Patients undergo surgery under general anesthesia and positioned in the supine position. The operator is left of the patient. The other set-up is as usual in a laparoscopic cholecystectomy.

After local anesthesia 4 incisions are made, allowing the same number of gates surgery. A 10mm 30 ° laparoscope (EndoEYE, Olympus, Pennsylvania United States) without accompanying trochard inserted next three 5mm instruments. Through the gate, the gallbladder midaxillaire stretched around the liver.

Then as usual the triangle of Callot and open structures in the triangle dissected to 'Critical View of Safety' is obtained, as described by Strasberg [2]. For clipping of cystic duct and artery cystica their usual 10mm clips used. Then the gallbladder in the normal way diathermisch leverbed dissected. Once the gallbladder was completely dissected by this incision below the navel removed. The fascia and skin are closed Monocryl and PDS respectively.

The technique LESS

Patients undergo surgery under general anesthesia and positioned in the "French position" with the operator between the legs. The other set-up is as usual in a laparoscopic cholecystectomy with four incisions.

After local anesthesia with the umbilical geëverteerd Kocherklem one on either side. The umbilicus is a small longitudinal incision of approximately 2 cm. The

TriPort \* (shown below) simply inserted through the abdominal wall. Insufflation is via an adherent to the TriPort \* tube with a tap. A 10mm extension 30 ° laparoscope (EndoEYE, Olympus, Pennsylvania United States) without accompanying trochard introduced next two 5mm instruments. This gives sufficient room for individual instruments side by side to move. In a Kirschner wire midclaviculairlijn the ninth rib stabbed in the abdomen. It is using an old-fashioned Enderpen, at the end has an eye, a curved hook. The fundus of the gallbladder can truly be hung on the hook as a coat on the coat. Provided these are only the serosa was derived does not usually gallekkage. It become fixated the gallbladder after the Kirschner wire was erected and externally fixed with a Kocher.

### **Study burden and risks**

2 Additional visits for the patient, one of 15-20 minutes before the operation for more detailed information and an extra time after surgery (three months) of 15 minutes and at that time an ultrasound of the abdominal wall (control breukjes)

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Patient on waitinglist for laparoscopic gallbladder removal

Age between 18 and 70 years

BMI < 35 kg/m<sup>2</sup>

### Exclusion criteria

In Prior history; Cholecystitis, ERCP, Upper GI surgery, other liver disease, Cancer in upper GI trackt, Alcohol or substance abuse

Participation in other research

Psychiatric condition

Unability to comply to study criteria

Patients without social network/ unable to care for themselves

Pregnancy

## Study design

### Design

|                     |                             |
|---------------------|-----------------------------|
| Study type:         | Interventional              |
| Intervention model: | Other                       |
| Allocation:         | Randomized controlled trial |
| Masking:            | Open (masking not used)     |
| Control:            | Active                      |
| Primary purpose:    | Treatment                   |

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-09-2010

Enrollment: 60  
Type: Anticipated

## Ethics review

Approved WMO  
Date: 27-09-2010  
Application type: First submission  
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID             |
|----------|----------------|
| CCMO     | NL33260.091.10 |