

# Randomised blind single centre study on morbidity and cost-effectiveness of two types of surgery for cholecystectomy

**Submission date**  
12/09/2005

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☒ Protocol

**Registration date**  
26/01/2006

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
11/01/2012

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Cees van Laarhoven

### Contact details

Department of Surgery  
St Elisabeth Hospital  
Hilvarenbeekseweg 60  
Tilburg  
Netherlands  
5022GC

## Additional identifiers

### Protocol serial number

Protocol 0031

## Study information

### Scientific Title

**Acronym**

SILAP (Small-Incision versus LAParoscopy)

**Study objectives**

1. No difference in complications between small-incision and laparoscopic cholecystectomy
2. Difference of 10% in direct costs

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Symptomatic cholecystolithiasis

**Interventions**

Small-incision versus laparoscopic cholecystectomy

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

1. Mortality
2. Complications
3. Costs

**Key secondary outcome(s)**

1. Pulmonary function
2. Health-related quality of life
3. Convalescence (return to work)

**Completion date**

01/04/2004

**Eligibility****Key inclusion criteria**

1. Patients with symptomatic cholecystolithiasis
2. Older than 18 years
3. Reasonable to good health as classified by the American Society of Anesthesiologists (ASA) grade I - II
4. Knowledge of the Dutch language
5. Signed informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Choledocholithiasis
2. Cholangitis
3. Acute cholecystitis
4. Known pregnancy
5. Moderate to severe systemic disease (ASA III or higher)
6. Previous upper abdominal surgery (which would exclude the patient from laparoscopic cholecystectomy)
7. Psychiatric disease
8. History of abdominal malignancy

**Date of first enrolment**

01/01/2001

**Date of final enrolment**

01/04/2004

**Locations****Countries of recruitment**

Netherlands

**Study participating centre****Department of Surgery**

Tilburg

Netherlands

5022GC

# Sponsor information

## Organisation

St Elisabeth Hospital (The Netherlands)

## ROR

<https://ror.org/04gpfvy81>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Foundation 'Gasthuisraad' (The Netherlands)

## Funder Name

Foundation for Scientific Research 'Midden-Brabant' (The Netherlands)

# Results and Publications

## 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	01/04/2008		Yes	No
<a href="#">Results article</a>	results	01/07/2008		Yes	No
<a href="#">Protocol article</a>	protocol	04/09/2009		Yes	No