

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

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Symptomatic cholecystolithiasis

Interventions

Small-incision versus laparoscopic cholecystectomy

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Mortality
2. Complications
3. Costs

Secondary outcome measures

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

Overall study start date

01/01/2001

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Two groups of 120 patients

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)

Sponsor details

Department of Surgery

Hilvarenbeekseweg 60

Tilburg

Netherlands

5022GC

Sponsor type

University/education

Website

<http://www.elisabeth.nl/>

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

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	01/04/2008		Yes	No
Results article	results	01/07/2008		Yes	No
Protocol article	protocol	04/09/2009		Yes	No