Early or delayed laparoscopic cholecystectomy after endoscopic sphincterotomy for combined cholecystolithiasis. A prospective randomised trial.

Submission date	Recruitment status No longer recruiting	Prospectively registered		
21/07/2006		☐ Protocol		
Registration date 21/07/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 08/01/2021	Condition category Urological and Genital Diseases	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr D. Boerma

Contact details

St Antonius Hospital Department of Surgery P.O. Box 2500 Nieuwegein Netherlands 3430 EM

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Early or delayed laparoscopic cholecystectomy after endoscopic sphincterotomy for combined cholecystolithiasis. A prospective randomised trial.

Acronym

LANS

Study objectives

Early laparoscopic cholecystectomy after endoscopic sphincterotomy for combined cholecystolithiasis, leads to less conversions as compared to laparoscopic cholecystectomy 6-8 weeks after sphincterotomy, and thus reduces morbidity and hospital stay.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

A prospective randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Combined cholecystolithiasis

Interventions

Patients will be randomised to undergo either early (within three days) or late (after 6-8 weeks) cholecystectomy

Intervention Type

Other

Phase

Primary outcome measure

Number of conversions to open cholecystectomy

Secondary outcome measures

- 1. Length of operation
- 2. Postoperative pain and performance scale
- 3. Complications of cholecystectomy
- 4. Hospital stay
- 5. Time until professional rehabilitation

Overall study start date

09/06/2006

Completion date

01/01/2008

Eligibility

Key inclusion criteria

- 1. Proven common bile duct (CBD) stones
- 2. Proven gallbladder stones
- 3. Successful sphincterotomy and stone extraction
- 4. Patients older than 18 years of age
- 5. Informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

96

Total final enrolment

96

Key exclusion criteria

- 1. Biliary pancreatitis
- 2. Acute cholecystitis
- 3. American Society of Anesthesiologists (ASA) IV and V patients

Date of first enrolment

09/06/2006

Date of final enrolment

01/01/2008

Locations

Countries of recruitment

Netherlands

Study participating centre St Antonius Hospital

Nieuwegein Netherlands 3430 EM

Sponsor information

Organisation

St Antonius Hospital, Department of Surgery (The Netherlands)

Sponsor details

P.O. Box 2500 Nieuwegein Netherlands 3430 EM

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/01jvpb595

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

St Antonius Hospital, Nieuwegein

Results and Publications

Publication and dissemination planNot 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	01/06/2010	08/01/2021	Yes	No