ISRCTN42981144 https://doi.org/10.1186/ISRCTN42981144

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

Submission date
21/07/2006

Recruitment status
No longer recruiting

Registration date
21/07/2006

Overall study status
Completed

Last Edited
08/01/2021

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

NL649, NTR710

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

Not Specified

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 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	01/06/2010	08/01/2021	Yes	No