

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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27342

Source

NTR

Brief title

LANS

Sponsors and support

Primary sponsor: none

Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Number of conversions to open cholecystectomy.

Secondary outcome

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

Study description

Background summary

This is a randomised trial among patients who are scheduled to undergo laparoscopic cholecystectomy after endoscopic sphincterotomy for combined choledochocystolithiasis. Nowadays, in most countries, surgery is planned 6 to 8 weeks after sphincterotomy. In over 20% of these patients the laparoscopic operation is converted to open surgery, whereas in patients who undergo laparoscopic cholecystectomy for uncomplicated symptomatic gallstones, conversion is necessary in only 5% of patients. The hypothesis of this trial is that the high conversion-rate in these patients can be lowered by performing the operation shortly after sphincterotomy, i.e. within 3 days. Patients who undergo successful sphincterotomy for CBD stones, and who have residual stones in the gallbladder, will be randomised to undergo either early (within 3 days) or late (after 6-8 weeks) cholecystectomy. Primary endpoint is the number of conversions in both groups.

Study objective

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

Intervention

Patients will be randomised to undergo either early (within 3 days) or late (after 6-8 weeks) cholecystectomy.

Contacts

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Eligibility criteria

Inclusion criteria

1. Proven CBD stones;
2. Proven gallbladder stones;
3. Successful sphincterotomy and stone extraction;
4. Patients older than 18 years of age;
5. Informed consent.

Exclusion criteria

1. Biliary pancreatitis;
2. Acute cholecystitis;
3. ASA IV and V patients.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated):	09-06-2006
Enrollment:	96
Type:	Anticipated

Ethics review

Positive opinion	
Date:	21-06-2006
Application type:	First submission

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
NTR-new	NL649
NTR-old	NTR710
Other	: N/A
ISRCTN	ISRCTN42981144

Study results

Summary results

N/A