

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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27342

Bron

Nationaal Trial Register

Verkorte titel

LANS

Ondersteuning

Primaire sponsor: none

Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of conversions to open cholecystectomy.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	09-06-2006
Aantal proefpersonen:	96
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	21-06-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL649
NTR-old	NTR710
Ander register	: N/A
ISRCTN	ISRCTN42981144

Resultaten

Samenvatting resultaten

N/A