Kumar clamp versus Olsen cAtheter for Laparoscopic intraoperative cholAngiography (KOALA)

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To assess whether cholangiography using the Kumar clamp is faster and easier than using the Olsen catheter.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gallbladder disorders
Study type	Interventional

Summary

ID

NL-OMON34943

Source
ToetsingOnline

Brief title
KOALA (kumar versus Olsen)

Condition

- Gallbladder disorders

Synonym
cholelithiasis, gall stones

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cholecystectomy, Intraoperative cholangiography, Kumar, Olsen

Outcome measures

Primary outcome

The main endpoint of the study is the time necessary for IOC, defined as the time from insertion of the instrument for cystic ductotomy (control arm) or the Kumar clamp (intervention arm) to the time that the x-ray arm is rolled out of the operative field.

Secondary outcome

The secondary endpoint is the surgeon's judgement of the ease of the procedure (measured by questionnaire).

Study description

Background summary

Laparoscopic cholecystectomy (LC) is the most commonly performed operation in abdominal surgery. A dreaded complication of the procedure is bile duct injury (BDI), which is associated with occasional mortality, often major morbidity, high costs and decreased long-term quality of life. Intraoperative cholangiography (IOC) has been shown to decrease the risk of BDI by 33 to 50%. It also doubles the proportion of BDI detected in an early stage and allows intraoperative detection of common bile duct stones. Although the IOC is part of standard procedure in the UMCG, there is resistance to the routine application of IOC in the Netherlands and other parts of the world. Reasons for this resistance include the sometimes cumbersome procedure of dissecting the cystic duct to insert the cholangiography catheter, and the extra operation time needed. Another disadvantage of the conventional technique is that it is only applicable once the cystic duct has been positively identified, which is in a relatively late phase of the procedure.

An alternative instrument for IOC is the Kumar clamp. This clamp was first described in 1992 but after one promising initial review has not been reported upon in the medical literature. The instrument consists of a clamp which is

placed over the base of the gallbladder and an attached needle which extends into the gallbladder into Hartmann*s pouch. The radiopaque contrast is then injected through the needle. The advantages of the instrument is that it does not require identification or dissection of the cystic duct. It can be applied in an earlier phase of the operation and may well decrease the time necessary for cholangiography.

Study objective

To assess whether cholangiography using the Kumar clamp is faster and easier than using the Olsen catheter.

Study design

A double blind (patient and investigator) two-armed randomized controlled trial.

Intervention

Patients in both arms of the study will undergo laparoscopic cholecystectomy using the standard critical view of safety technique. Patients in the control arm will undergo IOC in the standard manner using a cystic duct catheter. Patients in the intervention arm will undergo IOC using the Kumar clamp. If this technique fails to provide a satisfactory cholangiogram, conventional IOC will also take place.

Study burden and risks

The burden associated with participation is the use of an instrument that has not been previously used in the UMCG. However, it has been in use since 1995 and no extra risk has been reported resulting from its use. It is FDA approved, CE Mark and ISO Certified. Surgeons using the clamp will receive training in its use in the skills laboratorium from an abdominal surgeon with extensive experience with cholangiography.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients aged 18-70 with an indication for laparoscopic cholecystectomy with intraoperative cholangiography.

Exclusion criteria

Malignancies of the gallbladder.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Generic name:	Kumar clamp
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL30638.042.09