

# Kumar versus Olsen cIAmp for Laparoscopic cholAngiography (KOALA trial).

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON24651

### Source

NTR

### Brief title

KOALA

### Health condition

intraoperative cholangiography  
laparoscopic cholecystectomy  
intraoperatieve cholangiografie  
laparoscopische cholecystectomie

## Sponsors and support

**Primary sponsor:** University Medical Center Groningen

**Source(s) of monetary or material Support:** University Medical Center Groningen

## Intervention

## Outcome measures

### Primary outcome

1. Time necessary for intraoperative cholangiography (IOC), defined as the time between starting of preparation for IOC to the time that interpretation of IOC is completed;
2. Ease of the IOC procedure as measured on a visual analogue scale completed by the operator.

### **Secondary outcome**

The success rate of intraoperative cholangiography defined as contrast agent observed at least in the common bile duct.

## **Study description**

### **Background summary**

The KOALA trial is a randomized controlled trial to compare the Kumar clamp and the Olsen clamp for intraoperative cholangiography during elective laparoscopic cholecystectomy in terms of speed and ease of the cholangiography procedure.

### **Study objective**

Intraoperative cholangiography with the Kumar clamp is faster and easier than with the Olsen clamp.

### **Study design**

Intraoperative measurements and postoperative course until the first outpatient visit after discharge.

### **Intervention**

The intervention group will undergo intraoperative cholangiography (IOC) using the Kumar clamp.

The control group will undergo IOC using the Olsen clamp.

## **Contacts**

### **Public**

P. Box 30.001  
Vincent Nieuwenhuijs  
University Medical Center Groningen, Department of Surgery, Division of Abdominal Surgery  
Groningen 9700 RB  
The Netherlands  
+31 (0)50 3616161

### **Scientific**

P. Box 30.001  
Vincent Nieuwenhuijs  
University Medical Center Groningen, Department of Surgery, Division of Abdominal Surgery  
Groningen 9700 RB  
The Netherlands  
+31 (0)50 3616161

## **Eligibility criteria**

### **Inclusion criteria**

Adults scheduled for elective laparoscopic cholecystectomy with routine intraoperative cholangiography.

### **Exclusion criteria**

Conversion before cholangiography takes place.

## **Study design**

### **Design**

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

## Recruitment

NL  
Recruitment status: Recruiting  
Start date (anticipated): 01-11-2010  
Enrollment: 50  
Type: Anticipated

## Ethics review

Positive opinion  
Date: 29-10-2010  
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	NL2466
NTR-old	NTR2582
Other	METc UMCG : 2009/339
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A