

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

Source

NTR

Brief title

SONAR-Trial

Health condition

Cholecystitis, Cholelithiasis, Laparoscopic Surgery, Quality and Safety, Video and Audio Recording

Sponsors and support

Primary sponsor :	Erasmus Medical Center
Source(s) of monetary or material Support :	Not applicable

Intervention

Outcome measures

Primary outcome

The availability of information regarding the essential steps of laparoscopic cholecystectomy

Secondary outcome

Quality of surgery

Study description

Background summary

Previous research has demonstrated that intraoperative video recording during surgery will provide an objective and more complete documentation of the surgical procedure.

In this study, we will evaluate the added value of video recording with synchronous audio recording of the operator's voice compared to the traditional narrative operative report in patients undergoing elective laparoscopic cholecystectomy.

Study objective

Intraoperative video recording combined with synchronous audio recording of the operator's voice during laparoscopic cholecystectomy will more adequately document the essential steps of the surgical procedure compared to the narrative operative report alone.

Study design

During the procedure: from initial introduction, until disconnection of the endoscope at the end of the procedure

Intervention

- Intraoperative video recording of the surgical procedure using the available endoscopy equipment
- Simultaneous intraoperative audio recording of the operator's voice using a wearable microphone

Contacts

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Eligibility criteria

Inclusion criteria

- Patients aged 18 years or older
- Elective laparoscopic cholecystectomy procedure

Exclusion criteria

- Study cases with incomplete video recordings
- Study cases with incomplete audio recordings

Study design

Design

Study type :	Observational non invasive
Intervention model :	Parallel
Allocation :	Non controlled trial
Masking :	Open (masking not used)
Control :	N/A , unknown

Recruitment

NL	
Recruitment status :	Pending
Start date (anticipated) :	01-03-2018
Enrollment :	73
Type :	Anticipated

Ethics review

Positive opinion	
Date :	29-01-2018
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	NL6822

Register

NTR-old

Other

ID

NTR7008

: MEC-2018-1154

Study results

Summary results

van de Graaf FW, Lange MM, Menon AG, O'Mahoney PR, Milsom JW, Lange JF. Imaging for Quality Control: Comparison of Systematic Video Recording to the Operative Note in Colorectal Cancer Surgery. A Pilot Study. Ann Surg Oncol. 2016 Dec;23(Suppl 5):798-803. Epub 2016 Sep 22. Erratum in: Ann Surg Oncol. 2016 Dec;23 (Suppl 5):1065. PubMed PMID: 27660256;
PubMed Central PMCID: PMC5149562.

Wauben LS, van Grevenstein WM, Goossens RH, van der Meulen FH, Lange JF.
Operative notes do not reflect reality in laparoscopic cholecystectomy. Br J Surg. 2011 Oct;98(10):1431-6. doi: 10.1002/bjs.7576. Epub 2011 Jun 1. PubMed PMID: 21633952.