

# Video recording of large bowel cancer to improve surgical quality

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON26809

### Source

Nationaal Trial Register

### Brief title

IQ-Trial

### Health condition

Surgery; laparoscopic surgery; colorectal cancer.

Chirurgie; laparoscopische chirurgie; colorectaal carcinoom

## Sponsors and support

**Primary sponsor:** Erasmus University Medical Center, Rotterdam, the Netherlands

**Source(s) of monetary or material Support:** Stichting Kwaliteitsgelden Medisch Specialisten (SKMS; Quality Foundation Funds Medical Specialists)<br>Olympus, the Netherlands

## Intervention

## Outcome measures

### Primary outcome

Availability of information according to predefined checklists

## **Secondary outcome**

Surgical characteristics

- Type of surgical procedure
- Laparoscopic, open or converted surgery
- Surgery duration in minutes
- Hand sewn or stapled anastomosis
- Type of anastomosis
- Perforation during surgery
- Blood loss in ml
- Amount of blood transfusions necessary
- Intra-operative surgical complications
- Intra-operative anesthetic complication
- Intra-operative medical complication
- Drain placement
- Stoma yes/no

Pathological characteristics

- Pathology Benign/pre-malignant/Malignant
- Proximal resection margin in mm
- Quality of TME resection
- Tumor size in cm
- In case of second tumor: Benign/pre-malignant/Malignant
- In case of second tumor: Proximal resection margin in mm

- In case of second tumor: Quality of TME resection
- In case of second tumor: Tumor size in cm
- Total number of lymph nodes
- Number of positive lymph nodes
- Pathological Tumor stage
- Pathological Nodal stage
- In case of second tumor: Pathological Tumor stage
- In case of second tumor: Pathological Nodal stage
- Pathological Metastasis stage

#### Postoperative characteristics

- Postoperative morbidity or mortality  $\leq 30$  days according to the Clavien Dindo classification
- Postoperative wound infection
- Postoperative intra-abdominal abscess
- Postoperative urinary tract infection
- Postoperative respiratory tract infection
- Postoperative cardiological complication
- Postoperative neurological complication
- Postoperative thrombosis (DVT/PE)
- Postoperative Ileus
- Time until first bowel movement (days)
- Postoperative bleeding
- Anastomotic leakage
- Time of postoperative stay in hospital

- Readmittance  $\leq 30$  days postop
- Oncological recurrence

## Study description

### Background summary

To evaluate the added value of peroperative video recording to the traditional written operative report in providing objective and more complete documentation of surgical procedures, systematic video recording is applied to patients undergoing elective colorectal cancer surgery.

### Study objective

The use of peroperative video recording increases the amount of accessible information concerning the surgical procedure and improves surgical quality due to the systematic approach of the procedure

### Study design

Up to 30 days postoperative.

### Intervention

Video recording of fragments of given surgical procedures according to predefined checklists

## Contacts

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## Eligibility criteria

### Inclusion criteria

- Patients aged 18 or older
- Elective laparoscopic colorectal cancer resection (right hemicolectomy, transverse colectomy, left hemicolectomy, sigmoid colectomy or anterior resection)

### Exclusion criteria

- Incomplete medical record
- Patient aged under 18 years old
- Unresectable tumor
- Incomplete video recording

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting

Start date (anticipated):	01-01-2016
Enrollment:	113
Type:	Anticipated

## IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Positive opinion	
Date:	29-06-2017
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	NL6368
NTR-old	NTR6552
Other	METC Erasmus MC : MEC-2012-344

## 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.