Comparison of laparoscopic procedures with and without the aid the AutoLap system - a Robotic Camera Holder

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The objective of this study is to evaluate the ability to reduce the number of OR personnel required while performing the following procedures: colon resections (right hemicolectomy, left hemicolectomy/sigmoid resection), anti-reflux/hiatal hernia...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON43195

Source
ToetsingOnline

Brief title
Comparison of laparoscopic procedures with and without the AutoLap system

Condition

- Gastrointestinal conditions NEC
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
coloncarcinoma/adenoma, diverticulosis/diverticulitis, gastroesophageal reflux disease, Hiatal hernia

Research involving
Human

Sponsors and support

Primary sponsor: Medical Surgery Technologies ltd
Source(s) of monetary or material Support: Medical Surgery Technologies ltd

Intervention

Keyword: AutoLap, Laparoscope, Steering

Outcome measures

Primary outcome

The success rate, in terms of the ability to successfully complete an elective general laparoscopic procedure, with one less person in the OR compared with the number of OR personnel used in routine laparoscopic procedures.

Secondary outcome

Duration of the operation, defined as the time from the first abdominal incision until the surgical procedure is completed (skin incisions are closed)

Number of times that the laparoscope was removed for cleaning

Baseline characteristics: age, sex, BMI, ASA score, comorbidities, surgical procedure and indication

Surgical characteristics: date of surgery, type of surgery, surgeon, intra-operative complications

Length of stay in the hospital, complications during hospitalization

Study description

Background summary

Laparoscopic surgery has become the preferred method for performing many

general surgery procedures. The popularity of laparoscopic surgery is mainly because of the advantages that it offers to the patient in terms of shorter hospital stay, shorter recovery time, improvements in cosmetic outcome, and decreased postoperative complications. Standard laparoscopic procedures are often performed by teams consisting of two or three surgeons and a surgical nurse. Increasing cost pressure within the health system has raised the need for manpower saving in the OR by using robotic systems.

Robotic active camera holders which have been developed provide steady camera movements and view during the procedure and may replace the assistant holding the camera. The AutoLap system, an image guided robotic active camera holder, enables the surgeon to fully control the laparoscopic camera movements during surgery using a small button which is affixed to his hand or the surgical tool, and subsequently direct the surgical view with less erroneous camera motions, providing steady camera movement and view during the laparoscopic surgery. Additionally, the use of the AutoLap system may reduce the amount of personnel needed in the operating room during surgery thus sparing valuable highly skilled personnel for other tasks.

Study objective

The objective of this study is to evaluate the ability to reduce the number of OR personnel required while performing the following procedures: colon resections (right hemicolectomy, left hemicolectomy/sigmoid resection), anti-reflux/hiatal hernia surgery with the AutoLap system compared with the standard operation.

Study design

Prospective, randomized controlled single center study, open label

Intervention

NA

Study burden and risks

Minimal / theoretical: damage to internal organs due to unexpected or rude movements of the endoscope and infection.

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

1) Aged * 18 years
2) Able to provide a written informed consent
3) Fit for standard laparoscopic general surgery

Exclusion criteria

1) Pregnancy
2) Contra-indications for laparoscopy
3) Obesity (BMI >35 Kg/m2)
4) Patient participates in any other clinical study 60 days prior to the start of the study and throughout the study duration

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-09-2016
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	AutoLap system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-07-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-06-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL56735.100.16