Safety and performance evaluation of the AutoLap system - a feasibility study

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The main objectives of this study are to evaluate the safety and performance of the AutoLap system in the following laparoscopic procedures: hernia repair, cholecystectomy, right colectomy, Nissen fundoplication and sigmoidresection. The AutoLap…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON39368

Source
ToetsingOnline

Brief title
Safety and performance of the AutoLap system

Condition

- Gastrointestinal signs and symptoms
- Gastrointestinal therapeutic procedures

Synonym
cholecystolithiasis, colectomie, gallstones, hernia repair, Nissen fundoplication

Research involving
Human

Sponsors and support

Primary sponsor: Medical Surgical technologies ltd
Source(s) of monetary or material Support: MST Medical Surgical Technologies;Ltd

Intervention

Keyword: AutoLap, Endoscope, Steering

Outcome measures

Primary outcome

Performance Evaluation:

- The ability of the AutoLap system to successfully move the laparoscope to the surgeon's desired position. Success is defined as bringing the laparoscope to the desired position in at least 85% of the required movements.

Parameters that relate to the performance of an endoscope during endoscopic surgery

1) System set-up time recording

2) Average total procedure time recording

3) Number of times that the laparoscope was removed for cleaning.

4) Usability - the AutoLap system usability in laparoscopic procedures will be assessed by a questionnaire.

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Secondary outcome

Safety Evaluation:

1) No conversion to open surgery from laparoscopic surgery due to using the AutoLap system.

2) No AutoLap system related operative complications that require further

clinical intervention.

Study description

Background summary

During Laparoscopic treatment of surgical diseases an assistant is typically required to hold and position the camera according to the commands of the surgeon.
The assistant*s ability to anticipate the next camera placement is not always optimal, and communication problems occasionally occur. Holding the camera may also be exhausting in long surgical procedures, leading to fatigue and, potentially, unsteady images. Furthermore, depth perception may be impaired when the surgeon is not directing the camera.
MST has developed the AutoLap system, an active laparoscope positioner. The AutoLap system is designed to hold and position the laparoscope during laparoscopic surgery. When the camera is in position, the AutoLap system holds the laparoscope steady as with any laparoscopic positioner. To maneuver the laparoscope to the desired position, the surgeon presses a single button, which is affixed to his hand or to the surgical instrument.

Study objective

The main objectives of this study are to evaluate the safety and performance of the AutoLap system in the following laparoscopic procedures: hernia repair, cholecystectomy, right colectomy, Nissen fundoplication and sigmoidresection. The AutoLap system will be evaluated in Smart Joystick mode.

Study design

Prospective, single arm (non-randomized), multicenter study involving up to 40 subjects in The Netherlands, Israel and Italy, who are planned for the following laparoscopic procedures: hernia repair, cholecystectomy, right colectomy, Nissen fundoplication and sigmoidresection.

Intervention

Laparoscopic cholecystectomy, hernia repair, right colectomy, Nissen fundoplication and sigmoidresection conform national guidelines

Study burden and risks

Minimal/theoretical: damage to internal organs due to unexpected or rude movements of the endoscope
potential benefits:
The AutoLap system is designed to enable full control of the surgeon on the desired field of view and of the surgical procedure, thus eliminating the limitation of dis-coordination between the surgeon and the camera holder, possibly providing an image which is more stable, and the ability to maximize the efficacy of the operation room personnel.

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 between 18 and 85 years of age who were scheduled for elective laparoscopic procedures: cholecystectomy, hernia repair, right colectomy, Nissen fundoplication and

sigmoid resection

Exclusion criteria

1. Previous upper abdominal surgery and contraindications to Pneumoperitoneum.
2. Pregnancy.
3. Obesity (BMI >35 Kg/m2).
4. Generalized peritonitis.
5. Septic shock from cholangitis

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-01-2014
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	AutoLap System
Registration:	No

Ethics review

Approved WMO

Date:	18-12-2012
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-04-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-11-2013
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	NL41349.100.12