Evaluation of the Follow me mode of the AutoLap system- a feasibility study

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The main objectives of this study are to evaluate the performance and ease of use of the Follow me mode of the AutoLap system during general and gynecological laparoscopic procedures.Study Procedures: No. & type. A total of 35 laparoscopic...

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

Summary

ID

NL-OMON40655

Source
ToetsingOnline

Brief title
Evaluation of the Follow me mode of the AutoLap system- a feasibility study

Condition

- Gastrointestinal conditions NEC
- Gallbladder disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
as mentioned in C21

Research involving
Human

Sponsors and support

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

Intervention

Keyword: AutoLap, Laparoscope, steering

Outcome measures

Primary outcome

Primary endpoints:

1)Number of successful *Follow Me* movements, which are measured as the ability of the AutoLap system to successfully move the laparoscope to the surgeon's desired position using Follow Me mode (see paragraph *10.1). A successful procedure is a considered as a procedure that was completed with the AutoLap system.

2)System set-up time - defined as the time required from covering the AutoLap system with the sterile drape until the CU is registered and the laparoscope camera is connected in the desired position for starting the procedure (the readiness of the AutoLap for use)

3)Length of procedure- Defined as the time from the first abdominal incision until the surgical procedure is completed (skin incisions are closed)

4)Number of times that the laparoscope was removed for cleaning

5)AutoLap evaluation questionnaire * The ease of use of the AutoLap system and the surgeon*s satisfaction from the AutoLap system will be evaluated by a questionnaire that will be filled by each surgeon after each procedure.

Secondary outcome

Secondary endpoints:

1)System repositioning: Number of times that the system was repositioned after the initial positioning along the bed rail.

Initial positioning is completed once the surgeon starts the procedure.

Additional assessment Surgeon*s learning curve for the use of the AutoLap

system will be evaluated based on the following parameters:

*Number of successful movements

*Number of required system*s repositioning

*System set-up time.

Study description

Background summary

Evaluation of the Follow me mode of the AutoLap system * a feasibility study.

Study objective

The main objectives of this study are to evaluate the performance and ease of use of the Follow me mode of the AutoLap system during general and gynecological laparoscopic procedures.
Study Procedures: No. & type. A total of 35 laparoscopic procedures will be performed in the study, in up to 4 centers in Europe and Israel. Procedure types include:
Cholecystectomy, fundoplication surgery, right hemicolectomy, Diaphragmatic hernia, laparoscopic adnexal surgery, excision of
endometriosis lesion and diagnostic laparoscopy procedures.

Study design

Study Design:Prospective, multi-center study, one arm, open label.

Intervention

not applicable

Study burden and risks

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

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.Signed and dated Informed Consent Form
2. Patients over 18 years who were scheduled for elective laparoscopic cholecystectomy fundopllication surgery, right hemicolectomy, diaphragmatic hernia, laparoscopic adnexal surgery, excision of endometriosis lesion and diagnostic laparoscopy procedures.

Exclusion criteria

1.Pregnancy
2.Extensive adhesions that will preclude routine laparoscopic surgical approach.
3.American Society of Anesthesiologist'classification >2

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):	17-11-2014
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Autolapsystem
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-11-2014
Application type:	First submission
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	NL50856.100.14