Teleflex Robotic Endoscope Control * TREC study

Published: 11-11-2013
Last updated: 24-04-2024

The study aims to determine the safety and efficacy of the steering module in a clinical setting.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON38903

Source
ToetsingOnline

Brief title
TREC

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
mucosal inspection, polyp detection

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Provincie van Overijsel onder het project de High Tech Health Farm.

Intervention

Keyword: colonoscopy, endoscopy, robotic, steering

Outcome measures

Primary outcome

The primary endpoints are safety and efficacy.The primary study parameters are the number of SAEs related to the procedure and the number of successful cecal intubations.

Secondary outcome

Secondary parameters are intubation time, total procedure time and the evaluation of the physician*s opinion on inspection effectiveness on a 5 point Likert scale.

Study description

Background summary

The flexible colonoscope is an effective tool in diagnostics and small therapeutic interventions of the digestive tract. However, controlling the endoscope is difficult and advanced therapeutic interventions will demand even more of the physician. Ruiter et al. (2012) introduced a remote steering module for complex interventions. Preliminary studies showed this system is effective, increases efficiency and raises satisfaction in a simulated environment. The module should also allow safe and effective scope manipulation in order to reach intervention sites throughout the bowel without the need to change instruments. We expect the steering module to enable safe and effective colonoscopy in patients.

Study objective

The study aims to determine the safety and efficacy of the steering module in a clinical setting.

Study design

This is a prospective cohort feasibility study. It includes a two-step design with a preliminary evaluation before continuing the second phase of the study.

Study burden and risks

There is no extra burden associated with participation. Risks of participation could be in longer procedure time due to the learning aspect. The investigator may decide to convert to the conventional steering principle in case of poor visibility of the bowel wall or patient discomfort due to a prolonged procedure time.

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 who are scheduled for a diagnostic colonoscopy exam.
Patients should be 18 years or older.

Exclusion criteria

patients not fulfilling standard criteria to undergo colonoscopy.
patients who had previous abdominal surggery.
patients in ASA class 3, 4 or 5.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-09-2014
Enrollment:	54
Type:	Actual

Medical products/devices used

Generic name:	Teleflex endoscope control system
Registration:	No

Ethics review

Approved WMO

Date:	11-11-2013

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL42931.018.13