Spiral endoscopy for incomplete colonoscopy

Published: 25-02-2010
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To determine the efficacy, safety and patient tolerability of spiral endoscopy for use in colonoscopy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal signs and symptoms
Study type	Observational invasive

Summary

ID

NL-OMON35114

Source
ToetsingOnline

Brief title
Spiral colonoscopy

Condition

- Gastrointestinal signs and symptoms

Synonym
colon diseases

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Incomplete colonoscopy, Spiral endoscopy

Outcome measures

Primary outcome

The primary endpoint is the proportion of subjects with complete colon examination to the cecum using spiral colonoscopy.

Secondary outcome

Secondary endpoints include endoscopic procedural data including time-to-cecum, total procedural time, rate of terminal ileal intubation, endoscopic diagnostic yield, data regarding safety and adverse events, and patient tolerability data assessed using a comfort/discomfort visual analogue scale.

Study description

Background summary

Complete examination of the colon is important for all patients undergoing colonoscopy. There are certain patient groups for whom completing colonoscopy to cecal intubation or ileocolonoscopy to terminal ileal intubation is particularly difficult. Currently, patients with failed colonoscopy need to undergo a repeat colonoscopy. Spiral endoscopy is a new endoscopic method developed for use in small bowel enteroscopy that has particular advantages making it a potentially very attractive tool for use in colonoscopy.

Study objective

To determine the efficacy, safety and patient tolerability of spiral endoscopy for use in colonoscopy.

Study design

Pilot study with a prospective, observational cohort design.

Study burden and risks

Study participation entails undergoing colonoscopy using the new spiral endoscopy method, which is expected to be faster than conventional colonoscopy

with a similar risk profile. The alternative for patients who decline study participation is to simply repeat conventional colonoscopy. Study participation also involves completing a visual analogue scale of comfort/discomfort before and after the procedure as well as one day post-procedure, and answering a brief telephone call 30 days post-procedure regarding any possible adverse events. The total expected time commitment to complete the visual analogue scales and for the telephone call is less than 5 minutes.

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) Adult patient 18 years-old or older
2) Able to read/write in Dutch
3) Previously attempted colonoscopy that failed to reach cecum

4) Previously attempted ileocolonscopy that failed to intubate the terminal ileum for patients with suspected Crohn*s disease.

Exclusion criteria

1) Age < 18 years
2) Unable to provide informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	25
Type:	Anticipated

Ethics review

Approved WMO

Date:	25-02-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL30436.078.09