Single- vs. double-balloon enteroscopy in small bowel diagnostics: A randomized controlled single-blind multicenter trial

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The primary aim of the present study is to compare the new SBE system with the standard DBE system with respect to completeness of visualisation and insertion depth of the small bowel, as well as complications during the procedure.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON32093

Source
ToetsingOnline

Brief title
SBE vs DBE in visualization of the small bowel

Condition

- Gastrointestinal conditions NEC

Synonym
gastrointestinal bleeding, M. Crohn localisation in the small bowel, refractory celiac disease, unexplained diarrhoea or abdominal complaints

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: double balloon enteroscopy, enteroscopy, single balloon enteroscopy, small bowel pathology

Outcome measures

Primary outcome

1. Comparison of completeness of visualization (%) of the small bowel by

combination of upper and lower balloon enteroscopy.

Secondary outcome

2. Comparison of small bowel insertion depth (cm)

3. complications during the procedure

Study description

Background summary

The small bowel has been a black box for gastrointestinal (GI) endoscopy as, until recently, most of the small bowel was not accessible with conventional endoscopes. Double-balloon enteroscopy (DBE) is an endoscopic procedure for visualizing the entire small bowel. The method was first described by Yamamoto and colleagues in 2001 (1). Both endoscopic diagnosis and treatment can be easily performed using DBE. The first larger series, recently published, demonstrate that DBE is feasible in visualizing large parts of the small bowel (2-4). Although DBE has widely been used routinely for examining the small intestine there are a few issues which may limit its use. The preparation and handling of the DBE-endoscope is often interpreted as being complex (such as attaching the balloon to the tip of the endoscope, inflating/deflating the two balloon systems).
Recently, a novel balloon enteroscope system has been developed using only a single balloon (single balloon enteroscope, SBE). SBE was designed to facilitate diagnosis and treatment of the small bowel. The endoscopist needs to manipulate only one single balloon; thereby, time and complexity for preparation of the system and for the examination itself may be reduced. However, the new SBE system may be less efficient for deep intubation of the small bowel and may cause adverse effects due to the hooking of the endoscope during straightening of the endoscope.

Study objective

The primary aim of the present study is to compare the new SBE system with the standard DBE system with respect to completeness of visualisation and insertion depth of the small bowel, as well as complications during the procedure.

Study design

The study is designed as a multicenter randomized controlled trial.

Study burden and risks

Nature and extent of the burden: There is minimally extent of the burden by asking the patient to fill in a quastionnaire.

Risk: The risk associaiated with participation is very low. The risk for an inflammation of pancreas is lower than the standard procedure (DBE). The risk for mucosal damages due to the hooking of the endoscope during straightening of the endoscopist is in theory higher. The latter risk is estimated low and not significant.

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

Individuals eligible for inclusion are patients referred for routine balloon enteroscopy where total enteroscopy is indicated.

Exclusion criteria

Age under 18 years
Inability to understand information for participation
Refusal of participation

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2008

Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	10-10-2008
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	NL23544.078.08