

Small bowel imaging COmparing MR Enteroclysis and Video CApsule with Double-Balloon Endoscopy; the COMRADE study

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Comparison of two new techniques for detection of small bowel pathology: MR enteroclysis and videocapsule enteroscopy with double-balloon enteroscopy with respect to diagnostic yield, accuracy of findings, and patient preference.

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

Summary

ID

NL-OMON30347

Source

ToetsingOnline

Brief title

The COMRADE study

Condition

- Gastrointestinal conditions NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym

M. Crohn, obscure gastrointestinal bleeding

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar

Source(s) of monetary or material Support: Schering AG;Duitsland;Siemens medical systems;Nederland;Foreest instituut;Alkmaar

Intervention

Keyword: double-balloon endoscopy, MR enteroclysis, Small bowel, Videocapsule

Outcome measures

Primary outcome

diagnostic yield, including location and nature of lesions. The pathologic findings in the small bowel of the different diagnostic methods will be correlated with each other to analyse location and nature of lesions. This will be assessed in two populations:

1. Patients with known or suspected Crohn*s disease. The findings of the two techniques will be compared to the double balloon endoscopy on these items: location, severity of Crohn*s activity, stenosis and complications
2. Patients with signs of chronic or repeated gastrointestinal bleeding with negative gastroscopy and colonoscopy. The findings of the two techniques will be compared to the double balloon endoscopy on these items: location of bleeding focus and characters of the lesion. The findings of the double balloon endoscopy will be used as the gold standard.

Secondary outcome

Patients* appreciation of the different diagnostic methods. This will be analysed by means of a questionnaire. The specific questions of each examination will be filled in before all examinations, 24 hours after the

specific examination and 5 weeks after all the examinations.

Study description

Background summary

So far there has been no study that compares videocapsule endoscopy and MR enteroclysis for common small bowel diseases and especially not with the improved reference standard double balloon endoscopy. Such a comparison is highly needed to select appropriate techniques for individual patients. Because the double balloon endoscopy is in accordance with standard endoscopy, it can be used as a gold standard method.

Study objective

Comparison of two new techniques for detection of small bowel pathology: MR enteroclysis and videocapsule enteroscopy with double-balloon enteroscopy with respect to diagnostic yield, accuracy of findings, and patient preference.

Study design

This will be a prospective study comparing two imaging techniques. MR enteroclysis will be performed at the department of Radiology of the Medical Centre Alkmaar. The double-balloon enteroscopy and videocapsule will be performed at the department of Gastroenterology of the Medical Centre Alkmaar and the department of Gastroenterology and Hepatology of the Erasmus Medical Centre Rotterdam.

Intervention

MR enteroclyse, dubbel ballon endoscopie, videocapsule

Study burden and risks

MR enteroclysis: The dosis radiation received in order to place the nasogastric tube is very small (less than one X-ray of the Thorax). The sound produced by the MRI is muffled by a headphone which can also produce music. The contrast agent administered, hardly ever causes an allergic reaction. To reduce the peristalsis of the small bowel the medicine and the contrast agent are administered at the same time. This medicine can be of influence on eye muscles, as a result of which sight will be blurred for a short time. It is therefore advised not to drive a car directly after examination. After examination the stool can be watery.

Videocapsule: While swallowing, the videocapsule does not cause any side effects. If stenosis of the bowel is suspected, a test capsule is swallowed, which can fall apart in the small bowel.

Double-balloon endoscopy: Because of the anaesthetic you will not be aware of the examination and possible pain will be suppressed. Almost all of the small bowel can be visualized internally, and in case of abnormalities a piece of tissue can be biopsied. In general an endoscopy has few side-effects. The chance of complications as a result of the endoscopy is less than 1 per 1000 endoscopies. Local anaesthetic can sometimes cause choking or a reflux resulting in pneumonia. This is why it is important to remain in the so-called stable lying on one's side. Apart from this there is a risk of bleeding during the taking of biopsies.

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. Patients of >18 and < 75 years
2. One of the following patient groups:
 - a. Patients with suspected Crohn's disease
 - b. Patients with Crohn's disease, in need of visualization of the small bowel because of suspected disease activity.
 - c. Patients with signs of chronic or repeated gastrointestinal bleeding with negative gastroscopy and colonoscopy
3. Patients must be able to give informed consent and the consent must be obtained prior to any study procedures

Exclusion criteria

Patients will be excluded in case of:

- Abdominal surgery in the 6 weeks prior to inclusion
- Pregnancy
- Breastfeeding
- Inability to swallow the video capsule
- Presence of a pacemaker or cardioversion device
- Severe concomitant disease with limited life expectancy
- A psychiatric, addictive, or any disorder that compromises ability to give truly informed consent for participation in this study.

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-10-2006

Enrollment: 80

Type: Anticipated

Medical products/devices used

Generic name: MRI;Videocapsule;Double-balloon endoscopy

Registration: Yes - CE intended use

Ethics review

Approved WMO

Date: 09-06-2006

Application type: First submission

Review commission: METC Noord-Holland (Alkmaar)

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	NL11250.094.06