

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23200

Bron

NTR

Verkorte titel

COMRADE

Aandoening

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.

Ondersteuning

Primaire sponsor: Schering AG, Christiane Pering, M.D.

Siemens Nederland, Ronald Prinsze

Overige ondersteuning: Foreest instituut, P. Kieviet, Alkmaar, The Netherlands.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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. For patients with known or suspected Crohn's disease of the small bowel, a comparison will be made for prevalence, location, severity of inflammatory lesions, and complications such as formation of stenotic lesions. For patients with gastrointestinal blood loss, the techniques will be compared for prevalence and location of bleeding foci and characters of the lesion. The findings at the double balloon endoscopy will be used as the gold standard.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

There has been no study so far that compared 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.

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.

Study population:

A total of 80 patients with suspected small bowel disease across 2 hospitals in the Netherlands will be included in this multicenter study; 40 patients with proven or suspected Crohn's disease, and 40 patients with signs of chronic or repeated gastrointestinal bleeding with negative gastroscopy and colonoscopy

Main study parameters/endpoints:

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.
 2. Patients with signs of chronic or repeated gastrointestinal bleeding with negative gastroscopy and colonoscopy.
- Patients' appreciation of the different diagnostic methods. This will be analysed by means of a questionnaire.
- Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
- MR enteroclysis: The dose radiation received in order to place the nasogastric tube is very small (less than one X-ray of the Thorax).

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: The chance of complications as a result of the endoscopy is less than 1 per 1000 endoscopies

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

1. MRI enteroclysis
2. Double balloon endoscopy
3. Videocapsule

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients of >18 and < 75 years
2. One of the following patient groups:
 - 2.1 Patients with suspected Crohn's disease
 - 2.2 Patients with Crohn's disease, in need of visualization of the small bowel because of suspected disease activity.
 - 2.3 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with suspected intra-abdominal abscess
2. Abdominal surgery in the 6 weeks prior to inclusion
3. Patients with clinical suspicion of high grade small bowel obstruction
4. Pregnancy

5. Breastfeeding
6. Inability to swallow the video capsule
7. Presence of a pacemaker or cardioversion device
8. Patients with a history of contrast media reaction and history of allergy (esp. asthma)
9. Severe concomitant disease with limited life expectancy
10. A psychiatric, addictive, or any disorder that compromises ability to give truly informed consent for participation in this study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2006
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	05-09-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL763
NTR-old	NTR774
Ander register	: 0503
ISRCTN	ISRCTN78685405

Resultaten

Samenvatting resultaten

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