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Small bowel imaging COmparing Magnetic Resonance enteroclysis and video cApsule with Double-balloon Endoscopy: the COMRADE study

Submission date 28/12/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 28/12/2006	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 24/03/2009	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
0503; NTR774

Study information

Scientific Title

Acronym
COMRADE

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

Please note that as of 02/10/2008 the anticipated end date was extended. The initial anticipated end date was 01/10/2008. As of 06/02/2009 the anticipated end date was again extended. The previous anticipated end date was 01/01/2009. As of 24/03/2009 inclusion to this trial is closed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from:
1. The Medical Ethics Review Board (Medische Ethische Toetsingcommissie Noord-Holland) on the 9 June 2006 (ref: M06-023).
2. The Medical Ethics Review Board (Medische Ethische Toetsingcommissie Erasmus Medical Center Rotterdam) on the 10th October 2006 (ref: MEC-2006-178).

Study design
Prospective study comparing two imaging techniques

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Small bowel pathology

Interventions
1. Magnetic resonance imaging (MRI) enteroclysis
2. Double ballon endoscopy
3. Video capsule

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
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 Crohns 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.

Key secondary outcome(s))
Patients appreciation of the different diagnostic methods. This will be analysed by means of a questionnaire. Patients will be asked to repeatedly fill out the same questionnaire, 24 hours before and after each examination and five weeks after all the examinations.

Completion date
01/06/2009

Eligibility

Key inclusion criteria
1. Patients of more than 18 and less than 75 years
2. One of the following patient groups:
2.1. Patients with suspected Crohns disease
2.2. Patients with Crohns disease, in need of visualisation 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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients with suspected intra-abdominal abscess
2. Abdominal surgery in the six 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 (especially 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

Date of first enrolment
01/10/2006

Date of final enrolment
01/06/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Medical Center Alkmaar
Alkmaar
Netherlands
1800 AM

Sponsor information

Organisation
Schering Nederland BV (Netherlands)

ROR
https://ror.org/05y28vr04

Funder(s)

Funder type
Research organisation

Funder Name
Foreest Institute (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration