

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/03/2009	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Multi-centre

Study setting(s)

Other

Study type(s)

Screening

Participant information sheet

Health condition(s) or problem(s) studied

Small bowel pathology

Interventions

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

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

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.

Secondary outcome measures

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.

Overall study start date

01/10/2006

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80

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)

Sponsor details

c/o Christiane Pering, M.D.
Van Houten Industriepark 1
Weesp
Netherlands
NL-1381

Sponsor type

Industry

Website

<http://www.schering.nl/scripts/nl/index.php>

ROR

<https://ror.org/05y28vr04>

Funder(s)

Funder type

Research organisation

Funder Name

Foreest Institute (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration