MR Colonography with different types of bowel preparation: A pilot-study in healthy volunteers.

Published: 26-09-2008
Last updated: 06-05-2024

The objective for this study is to investigate different types of techniques and strategies, in order to optimize scan-parameters, image quality and patient acceptance in Magnetic Resonance Colonography.

Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON32606

Source
ToetsingOnline

Brief title
MR Colonography : different strategies

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
colorectal carcinoma, large bowel cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bowel preparation, Dark Lumen, Healthy volunteers, MR Colonography

Outcome measures

Primary outcome

This study is a pilot study with volunteers assigned to seven strategies and is aimed to give a direction for a further study proposal. The main outcome parameter is image-quality (lumen homogeneity) using different types of dark-lumen colonography strategies.

Secondary outcome

Secondary outcome parameter is the acceptance of the preparation and MRC examination using different types of contrast-tagging and rectal enemas.

Study description

Background summary

In order to assess the accuracy of Magnetic Resonance Colonography (MRC), a number of comparative studies of MRC versus Conventional Colonoscopy (CC) have been performed. Most of these studies describe a high variety of used techniques, e.g. bright lumen, dark lumen, fecal tagging (FT), non-tagging, bowel cleansing and different types of rectal enemas, resulting in a wide range of observed sensitivity. At present the optimal scan parameters and bowel preparation, aimed at high image quality and minimized patient burden, are not known. To give direction towards a comparative study, first a pilot study is performed comparing some *main stream* strategies as well as new approaches.

Study objective

The objective for this study is to investigate different types of techniques and strategies, in order to optimize scan-parameters, image quality and patient acceptance in Magnetic Resonance Colonography.

Study design

Prospective pilot study. A cohort of 21 healthy human volunteers will be assigned to 7 types of different strategies (S) with the use of dark-lumen colonography. Group 1 will receive gadolinium as contrast agent for fecal tagging (S1), a standard preparation for bowel cleansing (S2) , oral barium (S3) and oral Telebrix (S7) as contrast agent for fecal tagging and air/CO2 rectally. Group 2 will receive a low-fiber diet (S4) and no rectal enema. Colonic distension is achieved by oral administration of an artificial sugar solution (Mannitol). Group 3 receives oral barium (S5) or a standard preparation for bowel cleansing (S6) and tap water rectally.

Study burden and risks

Risks for the subjects undergoing the MRC examination are minimal. MRC is a diagnostic procedure so there are no direct therapeutic effects. There is a minimal risk of a symptomatic bowel perforation. There is no benefit for the healthy volunteers, except for a remuneration (150 euro) and reimbursement of travel expenses. The outcome of this study will guide us towards a further study on minimal bowel preparation for MRC, aimed at combining low burden bowel preparation with high accuracy MRC for screening and surveillance programs.

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

Healthy volunteers (human) in the age of 18 - 75 years, who are willing to undergo MRC and bowel preparation and who want to give informed consent.

Exclusion criteria

- contraindications to undergo MRI (pacemakers, claustrophobia and pregnancy)
- contraindications for intravenous injection of Buscopan (including glaucoma or severe cardiac arrhythmia)
- contraindications for the usage of (iodine-based) Telebrix (including iodine contrast allergy, hyperthyroidism)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	21
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission

Review commission: METC Amsterdam UMC

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	NL24407.018.08