

Comparson of computed tomography colonography with magnetic resonance colonography for use in colorectal cancer screening.

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To compare the sensitivity and specificity of MR colongraphy with that of CT colonography for the detection of colonic neoplasms, compared to colonoscopy as "gold standard".

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Benign neoplasms gastrointestinal
Study type	Observational non invasive

Summary

ID

NL-OMON31981

Source

ToetsingOnline

Brief title

CTC versus MRC for colorectal cancer screening.

Condition

- Benign neoplasms gastrointestinal

Synonym

colonic polyps, colorectal adenomas

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: colorectal cancer, computed tomography colonography, magnetic resonance colonography, screening

Outcome measures

Primary outcome

Sensitivity and specificity of MRC, CTC and colonoscopy for adenomas and "advanced adenomas" in symptomatic patients.

Secondary outcome

Patient experiences during the 3 procedures (discomfort/pain, willingness to repeat procedure, preference for one or other procedure)

Study description

Background summary

Colorectal cancer is the second leading cause of cancer death in the Western world. The Dutch government stated in May 2006 that it should be possible to start colorectal cancer screening in 2010. The major outstanding issue is the choice of method of initial detection of polyps or cancers. Since 2005 promising results have been obtained with CT colonography as a less invasive screening method. Detection accuracy similar to colonoscopy has been reported. The disadvantage of the use of CT is the exposure to radiation. MRI would have an obvious advantage over CT in colorectal cancer screening in the lack of exposure to radiation but studies using MR colonography have been limited to small patient samples and it has never been directly compared to CT colonography.

This study aims to compare CT and MR colonography in symptomatic patients referred for investigation by colonoscopy. The overall sensitivity and specificity for colonic adenomas, sensitivity and specificity for advanced adenomas (>10mm or high grade dysplasia), and patients experiences and preferences during the 3 procedures will be assessed.

Study objective

To compare the sensitivity and specificity of MR colonography with that of CT

colonography for the detection of colonic neoplasms, compared to colonoscopy as "gold standard".

Study design

222 patients will undergo standard colonic preperation with laxatives and undergo both a CT colonography and an MR colonography on the same day. For both the colon will be insufflated with CO2 and an intravenous antispasmodic administered, after which 2 scans will be made in prone and supine position.

Study burden and risks

Patients will undergo 2 scans both lasting approximately 1/2 hour. Before this they will be required to take laxatives to clean the colon. During the 2 scans, an intravenous antispasmodic and an intravenous constrast agent will be administered and the colon will be inflated with CO2 via a rectal cannula.

Risks: radiocontrast allergy, bowel perforation bij insufflation (<1/5000), discomfort with bowel insufflation

Benefits: extracolonic lesions can be identified. Intracolonic lesions missed by colonoscopy can be identified.

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

Suspicion of a colorectal neoplasm.

Exclusion criteria

Under 18 years

unable to undergo a colonoscopy

Allergy to radiological contrast agents

Claustrophobia precluding an MRI scan

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 04-01-2010

Enrollment: 222

Type: Actual

Ethics review

Approved WMO

Date: 18-03-2009

Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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	NL23717.058.08