Diffusion-weighted whole-body imaging with background body signal suppression (DWIBS) for colorectal cancer screening

Published: 15-07-2008
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The aim of this study is to investigate whether DWIBS is appropriate for colorectal cancer screening.

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

Summary

ID

NL-OMON33589

Source
ToetsingOnline

Brief title
DWIBS for colorectal cancer screening

Condition

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

Synonym
colon cancer, Colorectal cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Colorectal cancer, Diffusion, Magnetic resonance imaging, Screening

Outcome measures

Primary outcome

Sensitivity, specificity, positive predictive value and negative predictive value of DWIBS (with 95% confidence intervals) for the detection of relevant colorectal lesions (carcinomas and polyps >= 6mm).

Secondary outcome

N.A.

Study description

Background summary

In the Western world colorectal cancer is the second most common cancer in women and the third most common in men. The lifetime incidence of colorectal cancer in people at average risk is 5% and the age standardised incidence rate is 44.3 per 100,000 population. Early detection of colorectal cancer significantly improves survival. Current screening techniques (among which faecal occult blood testing, sigmoidoscopy, colonoscopy, double contrast barium enema, and computed tomographic virtual colonoscopie) are a burden to the patient, have a risk of complications, and/or are not sufficiently accurate.
The recently developed diffusion-weighted whole-body imaging with background body signal suppression (DWIBS)-sequence is an MRI-technique with high potential for colorectal cancer screening. Compared to current screening techniques, advantages of DWIBS are its non-invasiveness (no contrast agents have to be applied), relatively little discomfort to the patient (no bowel preparation, no invasive, internal investigation), its safety (no risk of complications), the absence of radiation burden, an acceptable scanning time (approximately 20-25 minutes), and a relatively fast interpretation of the obtained images.

Study objective

The aim of this study is to investigate whether DWIBS is appropriate for

colorectal cancer screening.

Study design

This will be a unicenter, prospective, diagnostic cohort study (timeschedule: 24 months). 390 eligible patients will undergo a DWIBS-scan prior to the already scheduled colonoscopy.

Study burden and risks

The patient has to lie in the MRI-scanner for approximately 20-25 minuten. The MRI-scan is completely non-invasive and without any adverse side-effects.

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

-Patients who are planned to undergo a colonoscopy in the UMC Utrecht because of suspected colorectal cancer, and having at least one of the following symptoms/signs: rectal bleeding, change in bowel habit, inexplicable weight loss, abdominal pain, and/or anemia
-Age: 50 years and older
-Written informed consent

Exclusion criteria

-Patients with a general contraindication for MRI (including cardiovascular pacemakers, claustrophobia)
-Patients who have had a previous malignancy
-Patients who are pregnant or nursing
-Patients in whom therapy has already started

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):	05-03-2009
Enrollment:	390
Type:	Actual

Ethics review

Approved WMO

Date:	15-07-2008

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-02-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL23040.041.08