Diffusion-weighted whole-body imaging with background body signal suppression (DWIBS) for colorectal cancer screening: pilot and feasibility study

Published: 11-03-2008 Last updated: 07-05-2024

The aim of this study is to investigate whether DWIBS may be an appropriate technique for colorectal cancer screening.

Ethical review	Not approved
Status	Will not start
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational non invasive

Summary

ID

NL-OMON31707

Source ToetsingOnline

Brief title

DWIBS for colorectal cancer screening: pilot and feasibility study

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

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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 and specificity of DWIBS (with 95% confidence intervals) for the

detection of tumors (carcinoma/polyp).

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 may be an appropriate

technique for colorectal cancer screening.

Study design

This pilot study will be performed in one university medical center (timeschedule: 12 months). Eligible patients will undergo an MRI-scan (DWIBS-sequence), after having undergone a colonoscopy (the current standard diagnostic modality).

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)

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Inclusion criteria

-Patients with an endoscopically unremovable colorectal tumor, and patients who have undergone a colonoscopy and who do not have a colorectal tumor, in the UMC Utrecht -Age: 18 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
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	40
Туре:	Anticipated

Ethics review

Not approved

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Date:	11-03-2008
Application type:	First submission
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 CCMO

ID NL20433.041.08