Three different limited bowel preparation regimes for CT colonography: evaluation of image quality and patient acceptance

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To investigate what CTC iodine tagging-only bowel preparation gives a high image quality and readability of the CTC together with a high patient acceptance.

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

Summary

ID

NL-OMON32386

Source
ToetsingOnline

Brief title
CTC tagging study

Condition

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

Synonym
colorectal carcinoma, colorectal polyps

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, CT colonography, iodine contrast agent, patient acceptance

Outcome measures

Primary outcome

The main study endpoints are the homogeneity and density of the residual faeces, the amount of residual fluid and the quality of tagging in CTC*s and the patient acceptance in three patient groups that received different iodine tagging preparations.

Secondary outcome

Secondary endpoint is evaluation of the polyp detection in the three patient groups that received a different bowel preparation.

Study description

Background summary

For computed tomography colonography (CTC) bowel preparation different cathartic and/or tagging agents are used. Because the bowel preparation is often rated the most burdensome aspect of the examination by patients, it is important to minimize this. Tagging-only bowel preparations have a minimal catharsis, but it is also necessary that image quality remains sufficient for evaluation of the CTC.

Study objective

To investigate what CTC iodine tagging-only bowel preparation gives a high image quality and readability of the CTC together with a high patient acceptance.

Study design

This is a prospective cohort study. The study population consists of FOBT positive patients that are allocated to 3 patient groups that receive different bowel preparations and a low-fiber diet: In group 1 are patients that receive

3*50 ml iodine contrast agent; group 2 receives 4*25 ml iodine contrast; and group 3 receives 3*25 ml iodine contrast. After ingestion of the contrast agents patients receive a CTC and after 1 week a colonoscopy (which is standard procedure for all FOBT positives).

Study burden and risks

Risks for the subjects undergoing the CTC examination are minimal. CTC is a diagnostic procedure so there are no direct therapeutic effects. Diagnostic positive effects for the subject exist when polyps or carcinoma*s are found at the CTC that are not found primarily at optical colonoscopy. Treatment for polyps and/or carcinoma can follow after diagnosis which can lengthen the survival of the subject. Minimal risks on bowel perforation exist because an automatic CO2 insufflator is used to inflate the colon. Because a reduced radiation dose protocol is used, a reasonably low risk on radiation induced cancer exists. Furthermore no serious adverse events due to iodine oral contrast are expected. A group-related benefit of this diagnostic study is that due to a minimal bowel preparation for CTC, the burden of the CTC bowel preparation might be further diminished.

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

All patients who are tested positive in the framework of the ZONMW granted FOBT pilot study, who are willing to undergo colonoscopy and who want to give informed consent.

Exclusion criteria

Patients who had examinations for research purposes with radiation exposure in the last 12 months, iodine contrast allergy, hyperthyroidism and pregnancy.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	45
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	NL23716.018.08