The feasibility of colorectal cancer and polyp detection using dual energy computed tomography with iodine mapping: a pilot study

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To investigate the feasibility of imaging and measuring enhancement of colorectal cancers and polyps using iodine mapping after acquiring dual energy abdominal CT scan with intravenous iodine contrast in patients without bowel preparation.

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

Summary

ID

NL-OMON36398

Source ToetsingOnline

Brief title IOMAP

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms benign

Synonym

colorectal cancer, large bowel cancer

Research involving

Human

Sponsors and support

Primary sponsor: Bronovo Ziekenhuis Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: colorectal cancer, ct colonography, dual energy, iodine mapping

Outcome measures

Primary outcome

Visibility and measurability of colorectal cancer at an iodine map using no

bowel preparation and no colon distension.

Secondary outcome

Visibility and measurability of colorectal polyps at an iodine map using no

bowel preparation and no colon distension.

Technical failures and the reasons for technical failures.

Study description

Background summary

Colorectal cancer is the second cause of cancer related death in Europe. CT-colonography is one of the recommended tools for colorectal screening in some countries and considered as such in other countries. One of the main drawbacks of CT-colonography as a screening tool is the bowel preparation that causes diarrhoea and discomfort. This preparation, with mostly oral iodine contrast, is needed to create enough contrast of cancer and polyps as compared to bowel content. Although substantially less burdensome than extensive bowel preparation, this bowel preparation is still a drawback of CT-colonography. Recently, dual energy CT has been introduced into clinical practice. Dual energy CT can distinguish different materials by performing scans at two energy levels and analyzing the differences in attenuation between these scans. Iodine has much more attenuation at low energy levels and can therefore be distinguished well with this technique. An iodine map of the colonic wall can be constructed after a dual energy CT scan with intravenous contrast is performed. If *after intravenous contrast medium* colorectal cancer and polyps are visible at an iodine map, they can be differentiated from stool and this could obviate the use of any bowel preparation.

Study objective

To investigate the feasibility of imaging and measuring enhancement of colorectal cancers and polyps using iodine mapping after acquiring dual energy abdominal CT scan with intravenous iodine contrast in patients without bowel preparation.

Study design

Prospective observational pilot study

Study burden and risks

The participant will not be exposed to any procedure that would not have been performed in current clinical practice. A benefit for participants may be a slightly reduced radiation dose. A single dual energy scan uses a higher radiation dose as compared with a *normal* single energy scan. Because dual energy obviates the need for an unenhanced series, the total received radiation dose may be lower than in current clinical practice. The radiation committee of the AMC calculated that the effective radiation doses of both protocols are very similar.

Contacts

Public Bronovo Ziekenhuis

Bronovolaan 5 2597 AX Den haag NL **Scientific** Bronovo Ziekenhuis

Bronovolaan 5 2597 AX Den haag NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

> 18 years old
Recent diagnosis of colorectal cancer
Will be sceduled for pre-operative abdominal staging CT
Written informed consent
Known eGFR calculated from maximum 3 months old serum creatinin.

Exclusion criteria

Iodine contrast allergy Renal function impairment, defined as an eGFR < 40 mL/min Body mass index > 30 kg/m2 Pregnancy

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL Recruitment status:

Recruitment stopped

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Start date (anticipated):	22-03-2011
Enrollment:	30
Туре:	Actual

Ethics review

Approved WMO Date: Application type: Review commission:

21-02-2011 First submission METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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 NL34841.098.10