

Standard versus high definition colonoscopy.

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Assess of the effect of HD colonoscopy alone or when combined with different I-scan functions compared to standard colonoscopy with respect to adenoma detection rate.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20419

Bron

Nationaal Trial Register

Aandoening

adenoma
screening colorectal cancer
colonoscopy

Ondersteuning

Primaire sponsor: Maastricht University Medical Center

Overige ondersteuning: initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Adenoma detection rate (ADR): The total number of adenomatous lesions (histological proven) divided by the number of patients per arm in all four groups.

Toelichting onderzoek

Achtergrond van het onderzoek

Adenomatous polyps are precursors for colorectal cancer. Colonoscopy is considered to be the golden standard for the detection of colonic neoplasia. In theory, colon cancer can be prevented by removing all adenomatous polyps. However, there is a significant number of missed lesions, as assessed by back-to-back colonoscopy. This mis-rate can be attributed to lack of technique (short withdrawal time, insufficient bowel preparation) or due to technological causes like the quality of endoscopes to visualise small lesions and the possibility to look behind folds. Several technological innovations in both colonoscope design, performances and image processing are tested to improve colon visualisation and to lower the number of missed lesions. Data of studies regarding the effect on adenoma detection rate (ADR) by use of high definition (HD) endoscopes compared to standard colonoscopes are conflicting. This may result from differences in expertise of endoscopists, types of endoscopes and software applications. The ADR is the most frequently used primary outcome parameter with respect of screening of colorectal neoplasia and as indicator of quality assessment.

Recently, Pentax developed a digital mucosal enhancement function, called I-scan. This function is incorporated into Pentax HD colonoscopes. These endoscopes have the highest resolution available in flexible endoscopy nowadays. Several function modes are available for the enhancement of vessel structures and pit pattern. The mode that enhances the mucosal vessel architecture, thereby improving of detection of small mucosal lesions is called Surface Enhancement. Digital image processing with emphasis on certain wavelengths of white light like the Colon Mode will probably add additional mucosal and vascular details. The present study is designed to assess the effect of HD colonoscopy alone or when combined with different I-scan functions compared to standard colonoscopy with respect to adenoma detection rate.

Doel van het onderzoek

Assess of the effect of HD colonoscopy alone or when combined with different I-scan functions compared to standard colonoscopy with respect to adenoma detection rate.

Onderzoeksopzet

1. Single colonoscopy;
2. Questionnaire after 60 weeks.

Onderzoeksproduct en/of interventie

1. Group A: Standard colonoscopes;
2. Group B: HD colonoscopes;

3. Group C: HD colonoscopes and I-scan Surface Enhancement (SE) (level 4);
4. Group D: HD colonoscopes and I-scan Surface Enhancement (SE) (level 4) and I-scan Colon Mode.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

A. One of the following reasons for colonoscopy:

1. Abdominal complaints;
2. Chronic diarrhea;
3. Iron deficiency anemia/ positive fecal occult blood test;
4. (Family) history of adenomatous polyps of colorectal cancer;
5. Screening colonoscopy to prevent CRC.

B. Sex: both males and females;

C. Age: above 40 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous extended colon surgery;
2. Inflammatory bowel disease (IBD);
3. Hereditary polyposis syndromes;
4. Known gastrointestinal neoplasia before endoscopy (based on recent endoscopy or other imaging like CT).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2010
Aantal proefpersonen:	1472
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	30-03-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2141
NTR-old	NTR2265
Ander register	METC MUMC : MEC 09-2-96
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A