# 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**
NTR

**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. Questionaire 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

## Publiek

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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 |
| Blindering: | 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