Feasibility and accuracy of the Olympus Extra Wide Angle View colonoscope for the detection of colorectal lesions in comparison with the Exera III study

Gepubliceerd: 23-04-2014 Laatst bijgewerkt: 15-05-2024

Increased adenoma detection rate due to the enlarged colonoscopic view

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22448

Bron
NTR

Verkorte titel
EWAVE

Aandoening

Adenoma Miss Rate during colonoscopy

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: Olympus Medical Systems

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Adenoma detection rate of the Olympus Extra Wide Angle View colonoscope

Toelichting onderzoek

Achtergrond van het onderzoek

Colonoscopy is the gold standard for finding colorectal cancers and precursor lesions, adenomas. Unfortunately recent studies show there is still a high adenoma miss-rate with the current endoscopic techniques. Some adenomas hide behind valve and are therefore missed. Olympus developed a new device that provides the endoscopist an enlarged view. The expectation is that due to this enlarged view more adenomas are detected compared to conventional colonoscopy. The results will be compared with the results of the EXERA III study

Doel van het onderzoek

Increased adenoma detection rate due to the enlarged colonoscopic view

Onderzoeksopzet

01-03-2015 data analysis

Onderzoeksproduct en/of interventie

Colonoscopy with extra wide angle view colonoscope

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age greater than or equal to 18 years

- High risk for colorectal cancer: FOBT positive, personal or familial (first degree relatives) history of colorectal cancer or colorectal adenoma, patients with symptoms suggestive of colorectal neoplasm: rectal bleeding, recent change in frequency and consistency of stools.

- Status 1 and 2 of the ASA classification (see Appendix I)

- Signed informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Mental or physical condition that can adversely affect the preparation or conduct of the examination or which precludes compliance with the study and / or device instructions.

- Inability to undergo bowel cleansing for colonoscopy.

- Prior abdominal surgery of the gastrointestinal tract (other than uncomplicated appendectomy or cholecystectomy).

- Known or suspicion of inflammatory bowel disease.

- Known large (> 2 cm) colorectal polyp for polypectomy

- Colonic diverticulosis complication within 3 months prior inclusion.

- Very high risk for colorectal cancer, history of extensive polyposis, patients with known genetic disease (Familial Adenomatous Polyposis (FAP), Hereditary Non-Polyposis Colorectal Cancer (HNPCC)).

- Coagulation abnormalities or taking drugs affecting coagulation.

- Life threatening conditions

- Status > 2 of the ASA classification (see Appendix I).

- Renal insufficiency or any contraindication or medication contraindicating the administration of bowel cleansing.

- Female patients who are pregnant or nursing, or of childbearing potential and are not using adequate contraception.

- Participation in another clinical trial within 30 days prior to the Screening Visit or during this study.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2014
Aantal proefpersonen:	429
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	23-04-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41267
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4316
NTR-old	NTR4536
CCMO	NL46414.018.13
OMON	NL-OMON41267

Resultaten