

ETMI versus Chromoendoscopy in UC

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

Samenvatting

ID

NL-OMON22789

Bron

Nationaal Trial Register

Verkorte titel

FIND-UC

Aandoening

Longstanding ulcerative colitis, colonic neoplasia

Langdurige colitis ulcerosa, dikkedarm neoplasieën

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam

Overige ondersteuning: Olympus

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

(1) to compare neoplasia detection rates of autofluorescence imaging (AFI) vs. chromoendoscopy (CE) in patients with ulcerative colitis. (2) to define the mean number of

neoplastic lesions per patient.

Toelichting onderzoek

Achtergrond van het onderzoek

Randomized trial: consecutive patients with longstanding UC will be randomized to undergo surveillance colonoscopy with either ETMI or CE.

Doel van het onderzoek

CE and AFI are equally effective for the detection of neoplastic lesions in patients undergoing colonoscopic surveillance for UC. Also, the combined use of AFI plus NBI and the use of CE have an equal sensitivity and specificity for the differentiation of non-neoplastic and neoplastic mucosa.

Onderzoeksopzet

This multicenter trial will include 210 patients with longstanding ulcerative colitis. We are aiming to include the last patient one year after the start of the study (August 2014). It will take approximately three months time to analyze the data.

Onderzoeksproduct en/of interventie

In this RCT we are comparing ETMI (endoscopic tri modal imaging) with chromoendoscopy in the detection of colonic neoplasia in ulcerative colitis. ETMI is a new endoscopy technique where three types of techniques are incorporated in one device: white light endoscopy, narrow band imaging and autofluorescence imaging. Chromoendoscopy is the technique that nowadays is recommended in IBD (Inflammatory bowel disease) surveillance guidelines. This technique makes use of dye spray to enhance the surface of the colonic mucosa, which is time-consuming. There is data that ETMI is has similar performance as chromoendoscopy, but these two technique have never been compared in a randomised controlled trial.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- History of UC
- Longstanding disease: extensive colitis >8 years (Montreal E3); or left-sided colitis >15 years (Montreal E2)
- Age >18 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Change in bowel habits in the preceding two months (under maintenance therapy)
- Personal history of (partial) colectomy
- Clinically unfit for colonoscopy
- Proven genetic predisposition for colorectal cancer
- Currently known colonic neoplasia (e.g. referred patients or patients who refused treatment)
- Known non-correctable coagulopathy that precludes taking biopsies (international

normalized ratio

>2; or platelet count <50*10⁹), severe cardiopulmonary disease or renal failure)

- At introduction Mayo-score >1 in at least one of the bowel segments
- Poor bowel preparation (scoring <6 points on the Boston Bowel Preparation Scale) (24)
- No informed consent

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2013
Aantal proefpersonen:	210
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	04-07-2013
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	NL3900
NTR-old	NTR4062
Ander register	NL42930.018.12 : METC 2012_362
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A