Third generation autofluorescence endoscopy compared with conventional autofluorescence endoscopy for the detection of early neoplasia in Barrett’s oesophagus.

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

Samenvatting

ID

NL-OMON21252

Bron
NTR

Verkorte titel
TRAFI study

Aandoening

Barrett's oesophagus
early neoplasia

Barrett slokdarm
vroege neoplasie

Ondersteuning

Primaire sponsor: AMC Amsterdam
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Overall histological yield of AFI II and AFI III;
2. Targeted histological yield of AFI II and AFI III;
3. Number of patients diagnosed with HGIN/EC by AFI II and AFI III.

Toelichting onderzoek

Achtergrond van het onderzoek

In Barrett’s oesophagus (BO), autofluorescence imaging (AFI) suffers from high false-positive (FP) rates and improved targeted detection of high-grade intraepithelial neoplasia (HGIN) and early cancer (EC) by AFI can be compensated by obtaining random biopsies. Third generation AFI may improve detection of early neoplasia and reduce FP-rate. We hypothesize that the new AFI-III system – compared to the conventional AFI-II – enhances the distinction between early neoplasia and inflammation in BO and thus reduces the amount of false positive lesions, allowing for targeted sampling and better detection of early neoplasia in BO.

This is the first randomized crossover study comparing the third generation AFI system with the conventional AFI in a selected group of patients with BE with and without dysplasia. Patients with Barrett's oesophagus with and without early neoplasia will undergo regular diagnostic imaging endoscopy for the detection of early neoplastic lesions. Patients are subsequently randomized to undergo either first AFI II or AFI III endoscopy, followed by a second endoscopy with the other system, in the same session by a second endoscopist, blinded for the results of the first endoscopy.

Doel van het onderzoek

We hypothesize that the new AFI-III system – compared to the conventional AFI-II – enhances the distinction between early neoplasia and inflammation in BO and thus reduces the amount of false positive lesions, allowing for targeted sampling and better detection of early neoplasia in BO.

This is the first randomized crossover study comparing the third generation AFI system with the conventional AFI in a selected group of patients with BE with and without dysplasia.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Patients will undergo regular diagnostic imaging endoscopy for the detection of early neoplastic lesions. Patients are subsequently randomized to undergo either first AFI II or AFI III endoscopy, followed by a second endoscopy with the other system, in the same session by a blinded endoscopist for the results of the first endoscopy

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age over 18 years;

2. Prior diagnosis of BO defined as columnar lined esophageal epithelium upon endoscopy and intestinal metaplasia upon histological assessment of esophageal biopsies;

3. Confirmed diagnosis of EC, HGIN, LGIN or non-dysplastic BO;

4. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Active erosive esophagitis grade B or higher according to the Los Angeles classification of erosive oesophagitis [17]17;

2. Advanced neoplastic lesion (i.e. any lesion considered not amendable for endoscopic treatment based its endoscopic appearance);

3. Unable to undergo biopsy sampling (e.g. due to coagulation disorders, esophageal varices).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	84
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-01-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34541
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3094
NTR-old	NTR3248
CCMO	NL32287.018.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34541

Resultaten

Samenvatting resultaten
Curvers WL, Herrero LA, Wallace MB, e.a. Endoscopic tri-modal imaging is more effective than standard endoscopy in identifying early-stage neoplasia in Barrett’s esophagus. Gastroenterology. 2010;139(4):1106-1114.