Endoscopic Tri-Modal Imaging (ETMI) for the detection of early neoplasia in patients with Barrett’s esophagus (BE) in tertiary referral centers; a randomized cross-over multi-center study.

Gepubliceerd: 30-03-2007 Laatst bijgewerkt: 18-08-2022

ETMI improves the detection of early neoplasia in Barrett's esophagus.

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

Samenvatting

ID

NL-OMON24455

Bron
NTR

Verkorte titel
ETMIC

Aandoening

Barrett's esophagus
Autofuorescence imaging
Narrow band imaging

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam
Overige ondersteuning: Olympus Corp, Tokyo, Japan.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. The number of patients and the number of lesions with early neoplasia detected with SVE and ETMI;
2. The number of patients with early neoplasia detected with targeted biopsies only with ETMI and SVE.

Toelichting onderzoek

Achtergrond van het onderzoek

Endoscopic Trimodal Imaging is a new imaging device that incorperates high-resolution white light endoscopy with autofluorescence imaging and narrow band imaging. Our aim of this study is to compare ETMI with standard video endoscopy for the detection of early neoplastic lesions in Barrett's esophagus. In this study high-risk patients reffered for the work-up of high-grade dysplasia or early cancer will included. All prodedures will performed by expert endoscopists in this field in 4 tertiary referal centres for the endoscopic treatment of early Barrett's neoplasia. All patients will undergo two endoscopies (ETMI and SVE) perfromed by two different endoscopists with an interval of 6-12 weeks.

Doel van het onderzoek

ETMI improves the detection of early neoplasia in Barrett's esophagus.

Onderzoeksproduct en/of interventie

In this study we will compare diagnostic endoscopy techniques for the detection of early enoplasia in Barrett's esophagus. These techniques are standard video endoscopy (the current standard) and
Endoscopic Tri-Modal Imaging (ETMI). Patients will undergo two consecutive endoscopies in an interval of 8-12 weeks. One of the two aformentioned techniques will be randomly assigned to the first procedure, the second procedure will subsequently be performed with the other technique by a second endoscopist.
The primary outcome will be the number of lesions and patients with early neoplasia detected with standard video endoscopy and ETMI.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age > 18 years;
2. Prior diagnosis of BE defined as the presence of columnar lined epithelium in the tubular esophagus with specialised intestinal metaplasia on histological investigation;
3. Prior diagnosis of high-grade dysplasia or early cancer that was endoscopically inconspicuous according to the referring physician. Review of the pathology slides is not required for inclusion;
4. A minimum Barrett's length of C>2M>2 or C<2M>4 according to the Prague C&M classification of the endoscopic appearance of BE;
4. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Presence of active erosive esophagitis > grade A according to the Los Angles classification of erosive esophagitis;
2. Description of an endoscopically visible suspicious lesion in the Barrett's segment in the referring center;
3. Presence of conditions precluding histological sampling of the esophagus (e.g. esophageal varices, coagulation disorders, anticoagulant therapy);

4. At the first endoscopy: the presence of a type 0-I or type 0-III lesion or a lesion that, according to the discretion of the endoscopist, does not allow a delay in intervention for a period of 6 weeks (interval between the two cross-over endoscopies).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2007
Aantal proefpersonen:	84
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-03-2007
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	NL921
NTR-old	NTR945
Ander register	:
ISRCTN	ISRCTN68328077

Resultaten

Samenvatting resultaten
Curvers WL, Wong Kee Song LM, Wang K, Gostout CJ, Wallace MB, Wolfsen HC, Ragunath R, Fockens P, Bergman JJ. Endoscopic Tri-Modal Imaging (ETMI) for the Detection of Dysplastic Lesions in Barrett's Esophagus; a multi-centre feasibility study. Endosc 2006; 38 (suppl II) A34.