EQMI-trial: Endoscopische Quad-Modal Imaging en moleculaire eindpunten ter opsporing van vroege neoplasie in Barrett oesophagus.

Gepubliceerd: 29-04-2009 Laatst bijgewerkt: 13-12-2022

1. In Barrett Esophagus (BE), probe-based laser endomicroscopy (pCLE) provides better correlation with the histological diagnosis compared to detailed inspection with Narrow Band Imaging (NBI), reducing the high rate of false-positive findings with...

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

Samenvatting

ID

NL-OMON21510

Bron
NTR

Verkorte titel
EQMI

Aandoening

Barrett oesophagus, refluxoesophagitis, Barrett oesophagitis, oesophaguscarcinoom, intestinal metaplasia, high grade dysplasia

Ondersteuning

Primaire sponsor: To be determined
Overige ondersteuning: To be determined

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

ENDPOINTS REAL-TIME IMAGING:
1. Correlation of real-time NBI vs. pCLE with histology;
2. Reduction of the false-positive rate of WLE+AFI with NBI vs. pCLE;

ENDPOINTS MOLECULAR ANALYSIS:
1. Correlation of AFI directed biopsies and yield of molecular abnormalities compared to random biopsies;
2. Correlation of AFI patterns and molecular abnormalities in BE;
3. Show that AFI increases detection of molecular markers with greater sensitivity and specificity than EQMI detection of dysplasia.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective:
In patients with Barrett esophagus (BE) undergoing surveillance or work-up endoscopy for early neoplasia, we aim to evaluate if endoscopic quad-modal imaging (EQMI), consisting of endoscopic tri-modal imaging (ETMI) combined with probe-based laser endomicroscopy (pCLE), increases the accuracy of detecting early neoplasia. In addition, we aim to determine the correlation between endoscopic patterns identified with EQMI and molecular markers of disease stage and progression

Background:
Endoscopic surveillance of BE patients is recommended to detect high-grade dysplasia (HGD) or early cancer (EC) at a curable stage. With standard endoscopy, however, it is difficult to distinguish areas with HGD/EC. In the absence of visible lesions, random biopsies are obtained for histological assessment of neoplasia, but random biopsies may miss dysplastic lesions (sampling error). The endoscopic detection of early neoplasia may be improved by the use of ETMI; a system that incorporates white light endoscopy (WLE) and autofluorescence imaging (AFI) for primary detection of early neoplasia and allows for targeted imaging of suspicious areas with narrow-band imaging (NBI). In a recent international multicenter study, AFI increased the sensitivity for detecting early neoplasia from 53% to 90% compared to WLE. Subsequent inspection with NBI of AFI+ areas reduced the false-positive rate of AFI from 81% to 26%. For EQMI a fourth imaging technique is added: pCLE, a new endoscopic imaging technique that allows for real-time histological evaluation of the mucosa [ref.2]. pCLE evaluation of AFI+ areas may be a better approach to reduce the high AFI FP-rate compared to NBI inspection. Furthermore, international research effort is aimed at identifying molecular markers to predict presence of neoplasia and to allow for risk stratification of BE surveillance patients [refs.3-5]. Several molecular markers have been accepted for this end,

but their clinical use is hampered by the fact that evaluation of molecular markers requires biopsy samples, and thus suffers from sampling error.
Currently, little is known about the correlation between endoscopic imaging patterns of neoplastic BE and underlying molecular abnormalities. Since the degree of neoplasia correlates with molecular changes on one side and with irregularity of the endoscopic image on the other side, we believe that by performing molecular studies on tissue targeted by EQMI, we will increase the detection rate of relevant molecular changes.

Methods:
In this prospective multicenter study, BE surveillance patients and BE patients with HGD/EC will be included. The BE is inspected using WLE, AFI, NBI and pCLE. Biopsies will be obtained from all suspicious areas for histology and molecular analysis. During the endoscopies all findings are recorded and video and still images are made from all suspicious areas for blinded evaluation at later stage.

Anticipated results:
the use of pCLE for detailed inspection of suspicious areas detected with WLE and/or AFI, increases the accuracy of detecting early neoplasia compared to detailed inspection with NBI. Furthermore, we anticipate to find a correlation in BE between EQMI patterns and molecular abnormalities which may allow for better risk stratification of BE surveillance patients.

Doel van het onderzoek

1. In Barrett Esophagus (BE), probe-based laser endomicroscopy (pCLE) provides better correlation with the histological diagnosis compared to detailed inspection with Narrow Band Imaging (NBI), reducing the high rate of false-positive findings with Autofluorescence imaging (AFI) and allowing for adequate real-time decision making;

2. AFI postive areas contain a higher rate of molecular abnormalities, even in areas that show no dysplasia upon biopsy. AFI may thus allow for the targeted detection of molecular abnormalities that predict malignant degeneration and be used for risk stratification of BE surveillance patients.

Onderzoeksopzet

1. 01.2010-07.2010: Patient inclusion, EQMI endoscopies and collection of biopsies. Final analysis and reports on the real-time imaging will be presented before 12.2010;

2. 07.2010-12.2010: Evaluation of videos/still images, results will be presented before 07.2011;

3. 10.2010-08.2011: Molecular studies, results will be presented before 12.2011.

Onderzoeksproduct en/of interventie

In this prospective multicenter study, BE surveillance patients and BE patients with HGD/EC

will be included. Successively, the BE is inspected using WLE, AFI, NBI and pCLE. Biopsies will be obtained from all suspicious areas for histology and molecular analysis. During the endoscopies all findings are recorded and video and still images are made from all suspicious areas for blinded evaluation at a later stage.

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age >18 yrs;

2. Circumferential BE >2 cm;

3. Non-dysplastic BE or low-grade dysplasia (LGD) (i.e. surveillance) or high-grade dysplasia (HGD)/ early cancer (EC) (i.e. work-up);

4. Signed informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Prior surgical or endoscopic treatment of esophageal neoplasia;

2. Erosive esophagitis (> LA grade B);

3. Inability to obtain biopsies;

4. Contraindication for fluorescein injection;

5. Unable to sign informed consent.

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:	01-01-2010
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-04-2009
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	NL1688
NTR-old	NTR1789
Ander register	MEC AMC : 09/073
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A