

Proteomics in early neoplasia in Barrett's esophagus: Biomarkers for early detection.

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By comparing protein profiles of dysplastic vs non-dysplastic Barrett epithelium, a novel biomarker for prediction of early neoplasia may be identified.

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

Samenvatting

ID

NL-OMON22993

Bron

NTR

Aandoening

Barrett's esophagus, Barrett's neoplasia, Barrett's cancer, Barrett's dysplasia, proteomics

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), department of Hepato- and Gastroenterology

Erasmus Medical Center (EMC), department of Neurology

Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Identification of peptides and proteins which could indicate presence of early neoplasia in a Barrett's esophagus.

Toelichting onderzoek

Achtergrond van het onderzoek

The purpose of this project is to compare the protein profile of Barrett's mucosa with and without early neoplasia in ER specimens in epithelial and stromal cells aiming to identify a biomarker indicating presence of early neoplasia in BE.

Doel van het onderzoek

By comparing protein profiles of dysplastic vs non-dysplastic Barrett epithelium, a novel biomarker for prediction of early neoplasia may be identified.

Onderzoeksopzet

May-2012: Interim analysis of 5 dysplastic vs 5 non-dysplastic samples;

March-2013: Complete analysis of all obtained ER samples.

Onderzoeksproduct en/of interventie

Dysplastic group:

Non additional.

Non-dysplastic group:

Endoscopic resection (ER-cap technique) of non-dysplastic Barrett's esophagus.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria 'dysplastic' group:

1. Scheduled ER for Barrett's esophagus containing HGD or early cancer;
2. Review of biopsies and histopathology specimens by an expert local pathologist;
3. Written informed consent.

Inclusion criteria 'non-dysplastic' group:

1. Scheduled surveillance endoscopy for Barrett's esophagus without dysplasia;
2. No dysplasia in biopsies, or biopsies 'indefinite for dysplasia' during at least the last two years;
3. No visible abnormalities in Barrett's esophagus in the two most recent surveillance endoscopies;
4. Review of biopsies and histopathology specimens by an expert local pathologist;
5. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria 'dysplastic' group:

1. In case histopathological assessment of the frozen half of the ER specimen is necessary for clinical decision making, the specimen will be retrieved from the Barrett's research tissue bank and further processed for clinical care.

Exclusion criteria 'non-dysplastic' group:

1. Patients that are not suitable candidates for ER because of co-morbidity.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-04-2011
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	18-01-2012
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	NL3095
NTR-old	NTR3249
Ander register	METC AMC : 11/096
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A