A randomized trial comparing the ER-cap technique and the multiband mucosectomy technique for piecemeal endoscopic resection of early Barrett neoplasia.

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We hypothesize that endoscopic resection (ER) of early neoplasia arising in Barrett esophagus (BE) using the multiband mucosectomy (MBM) technique is equally effective in removing early neoplasia, but may be faster, cheaper and possibly safer than...

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

Samenvatting

ID

NL-OMON25855

Bron
Nationaal Trial Register

Verkorte titel
RLC-trial

Aandoening

Barrett esophagus; Barrett oesophagus; Barrett neoplasia; high-grade dysplasia; early cancer; endoscopic resection; ER-cap technique; multiband mucosectomy technique

Ondersteuning

Primaire sponsor: Academic Medical Center,
Department of Gastroenterology and Hepatology.
Overige ondersteuning: fund=initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Rate of radically resected lesions;
- Number and severity of complications.

Toelichting onderzoek

Achtergrond van het onderzoek

This study will be performed at the AMC in Amsterdam, St. Antonius Hospital in Nieuwegein, Catharina Hospital in Eindhoven and the Gasthuisberg in Leuven.

Endoscopic resection (ER) is an important treatment modality for patients with Barrett esophagus (BE) containing high-grade dysplasia (HGD) or early cancer (EC). The most widely used ER technique, the ER-cap technique, requires submucosal lifting and prelooping of a snare in the cap, making it technically demanding and laborious when used for piecemeal resections. In addition, a new snare is needed for every resection.
The newer multi-band mucosectomy (MBM) technique uses a modified variceal band ligator and requires no submucosal lifting or prelooping of a snare, and multiple resections can be performed with the same snare. Aim of this study is to prospectively compare ER-cap and MBM for piecemeal ER in BE.

A total of 80 patients with BE-HGD/EC scheduled for piecemeal ER will be included. After delineation of the area to be resected, patients will be randomized to ER-cap or MBM. Assessment criteria are: number of resections/procedure, procedure time, time/resected specimen, complications, maximum diameter of specimens, and costs of disposables.

We hypothesize that both techniques will be equally effective, but MBM may be quicker, cheaper and may even be associated with less complications.

Doel van het onderzoek

We hypothesize that endoscopic resection (ER) of early neoplasia arising in Barrett esophagus (BE) using the multiband mucosectomy (MBM) technique is equally effective in removing early neoplasia, but may be faster, cheaper and possibly safer than the standard ER-cap technique.

Onderzoeksopzet

The patient will be randomized and treated in the same endoscopy session.

Onderzoeksproduct en/of interventie

Patients are randomized to undergo endoscopic resection using either the standard ER-cap technique, or the newer multiband mucosectomy technique.

Contactpersonen

Publiek

Academic Medical Center
Bldg. C2-210, Meibergdreef
J.J.G.H.M. Bergman
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5669111

Wetenschappelijk

Academic Medical Center
Bldg. C2-210, Meibergdreef
J.J.G.H.M. Bergman
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5669111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. BE with biopsy proven high-grade dysplasia (HGD) and/or early cancer (EC);

2. In case of visible lesions: type 0-IIa, 0-IIb, 0-IIc, or combinations of these types;

3. No suspicion of submucosal invasion on endoscopy or endosonography;

4. No signs of lymph node and/or distant metastases on endosonography and CT-scanning of thorax and abdomen;

5. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Lesion with suspicion on submucosal invasion;

2. Unable to give informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2005
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	05-09-2008
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	NL1375
NTR-old	NTR1435
Ander register	: MEC05/160
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A