MBM vs Cap for early esophageal squamous neoplasia.

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

Samenvatting

ID

NL-OMON25667

Bron
Nationaal Trial Register

Aandoening

esophageal squamous cell neoplasia

Ondersteuning

Primaire sponsor: AMC Amsterdam
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. The percentage of subjects with complete endoscopic removal of the qualifying lesion including pre-randomisation markers at the first ER section;
2. The percentage of subjects with no HGIN or ESCCA in biopsies obtained within 1-cm of the ER scar at 3 months follow-up.

Toelichting onderzoek

Achtergrond van het onderzoek

Endoscopic Resection (ER) for oesophageal highgrade intraepithelial neoplasia (HGIN) or intramucosal cancer (OSCC) with the ER-cap technique is technically difficult, requires submucosal lifting and multiple snares for piecemeal resections. Multi Band Mucosectomy (MBM) is an easy-to-use ER-technique and may be the modality of choice in China, where OSCC is extremely prevalent. We hypothesize that ER-cap and MBM will be equally effective and safe for piecemeal ER in selected patients. Piecemeal ER using the ER-cap, however, is technically more difficult and requires a higher number of disposables. We, therefore, hypothesize that MBM for piecemeal ER will reduce procedure time and cost significantly compared to ER-cap. From a clinical perspective MBM would be a valid alternative to ER-cap if a significant reduction of procedure time and cost were found while maintaining a success rate that is comparable to the ER-cap technique.

Patients with HGIN/OSCC and no signs of submucosal invasion or metastatic disease will be included. Lesions are delineated with electrocoagulation and resected with MBM or ER-Cap.

Doel van het onderzoek

We hypothesize that MBM may have significant advantages over the ER-cap technique, especially in countries where endoscopic expertise is limited.

The aim of this study was to assess the feasibility, safety and effectiveness of the MBM technique for piece-meal ER of early mucosal squamous cell neoplasia of the oesophagus and to randomly compare the MBM technique to the ER-cap technique.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Endoscopic resection of early esophageal neoplastic lesions by either MBM or ER-cap technique.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Subject is 18-85 years of age, inclusive;

2. A lesion in the squamous esophagus that is visible with white light endoscopy and contains a type 0-IIa, 0-IIb and/or 0-IIc component;

3. After Lugol’s staining the lesion and surrounding USLs (i.e. the treatment area; TA) measures ≥2cm and ≤6cm and encompasses ≤2/3 of the circumference;

4. A histological diagnosis of HGIN or ESCCA in biopsies obtained anywhere from the TA;

5. No infiltration into the submucosa or beyond or metastatic disease on endoscopic ultrasound (EUS) and CT-scan of thorax and upper third of the abdomen;

6. Subject is eligible for treatment and follow-up endoscopy and biopsy as required by the protocol;

7. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Any type 0-I or 0-III lesion in the esophagus;

2. Any other neoplastic lesion in the squamous esophagus that is visible with white light endoscopy and can not be included in the TA to meet its maximum size requirements;

3. Any unstained lesion after Lugol’s staining elsewhere in the esophagus that can not be included in the TA to meet the its maximum size requirements and contains HGIN or ESCC upon biopsy;

4. Any N or M positive status;

5. Any prior endoscopic resection or endoscopic ablation therapy of the esophagus within a 3 cm range of the TA;

6. Any history of a non-squamous cell cancer of the esophagus, or any history of a squamous cell cancer of the esophagus (any stage) prior to 12 months before screening for this trial;

7. Any prior radiation therapy to the esophagus;

8. Any previous esophageal surgery, except fundoplication without complications (i.e. no slippage, dysphagia, etc).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland Status:	Werving gestart
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-01-2012
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	NL3092
NTR-old	NTR3246
Ander register	METC AMC : 09-38/333
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
Pouw RE, van Vilsteren FGI, Peters FP, et al. Randomized trial on endoscopic resection-cap versus multiband mucosectomy for piecemeal endoscopic resection of early Barrett's neoplasia. Gastrointest. Endosc. 2011;74(1):35-43.