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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25855

Source
Nationaal Trial Register

Brief title
RLC-trial

Health condition

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

Sponsors and support

Primary sponsor: Academic Medical Center,
Department of Gastroenterology and Hepatology.
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

- Rate of radically resected lesions;

- Number and severity of complications.

Secondary outcome

- Time per procedure;

- Number of resected pieces per procedure,

- Costs of disposables per procedure;

- Maximum diameter of resected specimens;

- Maximum thickness of submucosa in resected specimens.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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

Contacts

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

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

1. Lesion with suspicion on submucosal invasion;

2. Unable to give informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2005
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-09-2008

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1375
NTR-old	NTR1435
Other	: MEC05/160
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A