Endoscopic mucosal Resection versus Endoscopic subMucosal dissection fOr removal of Visible lesions in Barrett*s Esophagus with early neoplasia: a randomized controlled trial

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We aim to compare EMR and ESD for removal of visible lesions in Barrett*s esophagus.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON51866

Source
ToetsingOnline

Brief title
REMOVE RCT

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
Barrett esophagus; esophageal neoplasia

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Barrett's esophagus, endoscopic resection, endoscopic treatment, esophageal cancer

Outcome measures

Primary outcome

Primary endpoint is the proportion of patients with no evidence of residual or

local recurrent neoplasia during 12 months follow-up after baseline.

Secondary outcome

- Incidence of perforation

- Incidence of post-procedural bleeding

- Incidence of esophageal stenosis

- Procedure times

- Proportion of patients with endoscopically radical resection

- Cost-effectiveness

- Total number of ER endoscopies per patient

- Proportion of patients with (progression to) high-risk EAC

- Proportion of patients in whom additional non-endoscopic therapy is required

Study description

Background summary

The optimal technique for removal of visible dysplastic lesions in Barrett*s esophagus remains controversial. Endoscopic mucosal resection (EMR) is safe, effective, easy to apply, and has been the most widely used technique since 2008. Endoscopic submucosal dissection (ESD) is a more controlled dissection method with potential improved efficacy, but at the cost of higher technical

complexity.

Study objective

We aim to compare EMR and ESD for removal of visible lesions in Barrett*s esophagus.

Study design

Prospective, randomized study to evaluate two regluar treatment techniques

Intervention

Not applicable

Study burden and risks

Both techniques are assumed safe and effective for removal of visible lesions in Barrett*s esophagus in current clinical guidelines. EMR is the most widely used technique nowadays, and ESD may be more effective, but head-to-head comparisons are lacking. There is sincere doubt about which of the techniques is better, if any. We therefore assume there is no risk for suboptimal treatment for participants in either arm of the study. Patients undergo 1 year follow-up after resection, while guidelines suggest that direct ablation therapy could be considered. However, the frequent FU visits and careful assessment during each FU visit, as dictated in the protocol, prevent the risk for progression of disease during FU. Patients are also asked to complete a digital diary during the first days after baseline. Apart from removal of the lesion with an efficient technique, in line with standard care, there is no additional benefit for participants of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Patients age: >= 18 years
- Willingness to undergo both EMR or ESD
- Ability to provide written, informed consent (approved by IRB) and understand the responsibilities of trial participation
- BE with a single visible lesion with absence of signs of submucosal invasion on endoscopy, after evaluation by the adjudication committee.
- Minimum diameter of the lesion >=15mm (in either direction)

Exclusion criteria

- Patients with visible lesions with suspicion of submucosal invasion bases on assessment of the adjudication committee
- Patients with HGD in at least one random biopsy, before inclusion (i.e. during endoscopy in the referring center < 3 months before imaging, or during imaging endoscopy)
- History of esophageal surgery other than fundoplication
- History of esophageal ablation therapy or endoscopic resection
- Multiple visible lesions in the BE segment at baseline
- Uncontrolled coagulopathy with INR >2.0, thrombocytopenia with platelet counts < 50,000
- Subject has a known history of unresolved drug or alcohol dependency that would limit ability to comprehend or follow instructions related to informed consent, post-treatment in-structions, or follow-up guidelines
- Life expectancy <2 years

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-01-2023
Enrollment:	84
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	10-08-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-09-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-05-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT05276791
CCMO	NL80859.100.22