Prospective randomized comparison of EMR versus EMR followed by photodynamic therapy for the treatment of early barrett's cancer.

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In this project we will evaluate the added value of PDT after complete EMR in patients with prior HGD and EC in Barrett*s esophagus.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON31690

Source
ToetsingOnline

Brief title
P-BEC study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Barrett's cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

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

Intervention

Keyword: Barrett's esophagus, early cancer, endoscopic mucosal resection, high grade dysplasia, photodynamic therapy

Outcome measures

Primary outcome

The primary endpoint of this study will be the recurrence rate of histological

proven severe dysplasia or cancer after EMR or EMR and PDT.

Secondary outcome

·Complication rates of PDT: Complications are subdivided into procedural

(during PDT) and post procedural complications (after ending the procedure).

Complications are further subdivided into major and minor complications.

·Mortality rates within 30 days of intervention.

Study description

Background summary

Endoscopic mucosal resection (EMR) can remove high grade dysplasia (HGD) and early cancer (EC) within the Barrett's esophagus (BE). At the same time it is an effective way for staging the disease, as it allows the pathologist to assess the depth of malignant invasion with maximum precision. The risk of major complications, such as bleeding and perforation, are significant, but low in comparison with the risks of a surgical procedure.
Other endoscopic ablative therapies such as photodynamic therapy (PDT) and argon plasma coagulation have also been shown effective in removing the neoplastic and surrounding epithelium. PDT is typically used to treat larger surface areas. Through the inherent destruction of the tissue exposed, it does not provide a specimen for histopathologic evaluation; also the depth of destruction is limited.
However, there is a major concern for the development of recurrent or metachronous lesions after complete eradication of HGD and early-stage cancer, using different endoscopic techniques. In order to reduce the risk of recurrent

neoplasia a combination of modalities is commonly used. However, the additional yield of combined multimodality ablation is not well established and further investigation should be undertaken.

Study objective

In this project we will evaluate the added value of PDT after complete EMR in patients with prior HGD and EC in Barrett*s esophagus.

Study design

This is a single center prospective randomized study carried out in the Erasmus MC - University Medical Center Rotterdam. Patients with prior HGD and EC (Vienna Class IV lesions) in Barrett*s esophagus, after radical mucosal resection, will be randomly assigned to one of the two study arms. The first will receive PDT and the second will receive no additional therapy after EMR. Endoscopic control biopsies will be taken at 3 and 6 month after randomization, and subsequently every 6 months until 2 years of follow up.

Intervention

PDT: patients are given the photosensitizer 5-aminolevulinic acid at a dosage of 40 mg/kg. Subsequently PDT is performed with a dye-laser, tuned at a wavelength of 633 nm. The light is delivered to the esophageal mucosa via a balloon mounted cylindrical diffuser. After PDT, patients are instructed to avoid direct daylight by remaining inside and avoid excessive exposure to UV light through other sources for 36 hours after ingestion of ALA.

Study burden and risks

None. PDT is the current standard treatment. In case of recurrence, the patient will be referred to their treating physician for further treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients age >= 18 years treated for high-grade intraepithelial dysplasia and/or mucosal cancer with EMR, in whom follow-up biopsies do not show remaining severe neoplasia or malignancy

Exclusion criteria

* Patients unable or unwilling to give informed consent
* Coagulopathy uncorrected at the time of endoscopy or thrombocytopenia (<50 x 10 9 / l thrombocytes)
* Patients with elevated liver enzymes (more than 2 times the upper limit normal)· * Patients with known porphyria, achalasia, connective tissue disease, esophagial atresia and prior caustic esophagitis
* Patients previously treated for dysplasia or cancer of the esophagus
* Patients previously treated with radiotherapy involving the mediastinum or surgical treatment of the esophagus
* A Barrett segment longer than 7 cm
* Pregnant or lactating women, or women of childbearing potential not taking adequate contraceptives

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2008
Enrollment:	48
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Gliolan
Generic name:	5-aminolevulinezuur
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	23-04-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-06-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2008-001183-37-NL
CCMO	NL20918.078.08