Intensive endoscopic therapy versus conventional treatment for untreated benign anastomotic strictures after esophagectomy: a pilot and randomized controlled trial

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To prolong the dysphagia-free period and to reduce the number of endoscopic dilations for patients with newly diagnosed, untreated benign anastomotic strictures after esophagectomy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON42848

Source
ToetsingOnline

Brief title
INCA trial

Condition

- Gastrointestinal stenosis and obstruction
- Gastrointestinal therapeutic procedures

Synonym
benign esophageal anastomotic stricture; postsurgical esophageal stricture

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Esophageal stenosis, Esophagectomy, Gastrointestinal endoscopy, Surgical anastomosis

Outcome measures

Primary outcome

Dysphagia-free period.

Secondary outcome

Number of endoscopic dilations, technical success, procedure-related

complications, dysphagia scores and therapy satisfaction score.

Study description

Background summary

One of the major issues after esophagectomy is the development of a benign anastomotic stricture, which occurs in up to 43% of patients. Endoscopic bougie or balloon dilation is currently the standard treatment to resolve dysphagia caused by anastomotic strictures. However, patients usually require repeated endoscopies to achieve a satisfactory luminal diameter with endoscopic dilation and stricture recurrence is common (50%). We hypothesize that endoscopic combination therapy, including in- and excision of the stenotic fibrotic ring combined with steroid injections and bougie dilation, is more effective than standard repeated endoscopic bougie dilation.

Study objective

To prolong the dysphagia-free period and to reduce the number of endoscopic dilations for patients with newly diagnosed, untreated benign anastomotic strictures after esophagectomy.

Study design

A Dutch multicenter, two-stage clinical trial, including a (*phase-II*) pilot study followed by an open-label, randomized controlled trial comparing intensive endoscopic therapy with conventional repeated bougie dilation.

Intervention

Intensive endoscopic therapy (= investigational treatment):
a. Endoscopic in- and excision of the stenotic fibrotic ring using a needle knife catheter.
b. Followed by injection of 0.5 ml aliquots Kenacort 40 mg/ml (= 20 mg of triamcinolone per injection) into 4 quadrants of the lesion.
c. Hereafter, the incised stricture is subsequently dilated up to 16 mm with bougienage. At the end of the procedure, the lesion is inspected endoscopically and pictures are taken.
d. The patient is scheduled for an additional endoscopic dilation procedure within approximately 1 week (range 5-9 days) during which the patient will be dilated up to a luminal diameter of 18 mm using bougie dilators.

Conventional, repeated endoscopic bougie dilation (= control group):
Patients will be treated with endoscopic bougie dilation until a luminal diameter of 18 mm is reached. The endoscopic procedures will be scheduled within approximately 1 week (range 5-9 days) following one another.

Study burden and risks

The investigational treatment is supposed to prolong the dysphagia-free period and reduce the number of endoscopic dilations for patients with benign esophageal anastomotic strictures. Therefore, potential benefits for study subjects are a longer relief of dysphagia and a decrease in the number of endoscopic re-interventions.
The main risks of intensive endoscopic therapy are the occurrence of perforation and bleeding. These risks are expected to be low (< 2%).
The burden of study participation consists of telephone contact after 14 days and thereafter monthly until 6 months of follow-up for answering questions about dysphagia symptoms and therapy satisfaction. No additional hospital visits are foreseen.

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

• Untreated benign esophagogastric anastomotic stricture after esophagectomy.
• The stricture should be suitable for endoscopic incision:
- Diagnosed at least 6 weeks after esophagectomy, and
- Stricture length <= 1 cm.
• Dysphagia score >= 2 = ability to swallow semi-solid food or worse.
• Age > 18 years.
• Written informed consent for study participation.

Exclusion criteria

• Benign esophageal stricture other than an esophagogastric anastomotic stricture.
• Strictures with a morphology unsuitable for needle-knife incision, such as long (> 1 cm), irregulair or tortuous strictures.
• Previous endoscopic treatment of the esophageal stricture, such as bougie/balloon dilation, steroid injection, incision therapy or stent placement.
• Previous stent placement post-esophagectomy for anastomotic leakage.
• (Suspicion of) recurrent or metastasized esophageal cancer.
• Persisting postoperative esophageal fistula.
• Inability to discontinue anticoagulants or high-dose antiplatelet drugs at time of the

baseline procedure. Low-dose aspirin (max. 100 mg/day) may be continued.
• Known clotting disorder.
• Patients unable to provide written consent for the study.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-07-2017
Enrollment:	89
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Kenacort-A 40
Generic name:	triamcinolone acetonide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	11-10-2016
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-09-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29569
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2016-001853-41-NL
CCMO	NL57698.018.16
OMON	NL-OMON29569

Study results

Date completed:	05-04-2019
Actual enrolment:	15