A multicenter, double blind placebo-controlled randomised trial for benign esophageal anastomotic strictures: Savary dilation vs savary dilation with triamcinolon

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To compare Savary dilation with saline 0.9% injections (placebo) with Savary dilation with triamcinolon injections in patients with benign anastomotic esophageal strictures

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35193

Source
ToetsingOnline

Brief title
BASTA-study

Condition

- Other condition
- Gastrointestinal stenosis and obstruction

Synonym
benign anastomotic esophageal stricture, swallowing disorder

Health condition

Benigne anastomotsiche slokdarmstricturen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Anastomotic stricture, Dysphagia, Savary dilation, Steroid injection

Outcome measures

Primary outcome

-Median time to repeat dilation

-Success rate after 6 months follow-up (number of patients dysphagia free

within 3 dilation sessions)

Secondary outcome

- Mean number of dilatation sessions

- Dysphagia

- Complications

- Quality of life

- Patient*s satisfaction with treatment

Study description

Background summary

Dysphagia due to benign esophageal stricture formation can significantly impair quality of life. Adequate treatment of these strictures is of utmost importance. Dilation is the mainstay of this treatment and can be performed by balloon dilatation or by Savary Gilliard bougienage. Both treatments have shown to be equally effective and safe, however Savary Gilliard dilations are re-useable, making this a more cost-effective method.

Strictures can be classified according to complexity. In general, peptic strictures are simple, focal and straight and require only 1-3 dilations to relieve dysphagia. Complex strictures are longer (>2 cm), angulated, irregular or with a severely narrowed diameter. The most common complex strictures include anastomotic, post-radiation or caustic strictures. These strictures are frequently refractory to dilation and require multiple (>5) sessions sometimes at weekly intervals.
Stricture formation at the site of the anastomosis after esophagectomy is increasingly reported as a common cause of benign esophageal strictures, whereas reflux disease less frequently causes stricture formation, probably due to the increased use of PPI*s (proton pump inhibition).
Addition of intra-esophageal triamcinolon injections to dilatation was first mentioned in 1969, but this technique has only been increasingly employed over the last decade. Several prospective studies have demonstrated its use in dogs, adults and children. Triamcinolon was found to be safe and effective in lengthening the dilation-free interval and reducing the risk for recurrent stricture formation in patients with strictures of all causes, but also in prospective series with peptic or corrosive strictures solely. However, a major disadvantage of these studies is the lack of a randomised study design. Four randomized trials (of which one is only available in Portuguese language and one only published only in abstract form) have compared both mechanical and balloon dilators with intralesional steroid injections vs dilation alone. Two trials showed a significantly increased dilation free interval for the steroid arm and one showed an increase in stricture diameter in the steroid arm. In one study only 13% needed a re-intervention due to recurrent dysphagia in the steroid group whereas 60% needed re-intervention in the control group. This study included only patients with refractory peptic strictures, whereas the two other trials included patients of all sorts of strictures and patients with corrosive strictures, respectively. However, a trial including patients with anastomotic strictures alone has not yet been performed. In only one study, a standardized technique and symptom scoring system was applied and blinding of patients and effect investigators was adequately performed.

Study objective

To compare Savary dilation with saline 0.9% injections (placebo) with Savary dilation with triamcinolon injections in patients with benign anastomotic esophageal strictures

Study design

A multicenter, double-blind, placebo controlled randomized controlled trial

Intervention

Patients in treatment arm A will be treated with Savary Galliard dilation with

four intralesional saline 0.9% injections of 0.5 ml in all four quadrants and patients in treatment group B receive Savary dilation with four intralesional triamcinolon 0.5 ml injections 40 mg/ml in all four quadrants. Savary dilation will be performed untill a diamter of 16 mm is achieved. In case of pinpoint strictures, two or more dilation session are required within one week to achieve this diameter (without additional injections).

Study burden and risks

Patients will be asked to fill in a questionnaire on their symptoms before first treatment, and patients will be contacted by phone after t=2 weeks, t=1 month,t=3 months and t=6 months for another questionnaire. After one week patients will be contacted to inform about possible mild complications after the intervention. Furthermore, patients will document their dysphagia score daily for the first month, thereafter, they will document their dysphagia score once weekly only. No additional hospital visits or blood samples are required.
The main risks of dilation (with or without steroids) is hemorrhage or perforation (0.1-0.4%). Furthermore, during all reported dilations with steroid injections, only one case of local candida infection was reported, which was effectively treated with ketaconazol.
The potential benefit expected in the study arm will be a longer dilation free interval and less dilation sessions to achieve relief of dysphagia.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with dysphagia grade 2-4 (Atkinson Dysphagia score) after esophagectomy with gastric tube reconstruction and cervical anastomosis

Exclusion criteria

-Previous dilation
-Dysphagia due to (suspicion of) malignant tumour recurrence
-Patients unfit for upper endoscopy
-Active anastomotic leakage or infection
-Recent vaccination with *alive* vaccine
-During the acute phase of viral, bacterial or fungal infections
-Known gastric or duodenal ulcera
-Previous allergic reaction to one of the substances of Kenacort
-A known infection with tropical worms (such as Strongyloide) or parasites
-Outpatient visits during the following 6 months by one of both independent endoscopist, performing the procedure

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-02-2010
Enrollment:	58
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Kenalog
Generic name:	Triamcinolone acetonide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	21-09-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-12-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-01-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-03-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	

Date:	19-07-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	EUCTR2009-013259-31-NL
CCMO	NL29249.041.09