A multicenter, double blind placebo controlled randomized trial for Benign esophageal Anastomotic Strictures: Savary dilation vs savary dilation with TriAmcinolon.

No registrations found.

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

Summary

ID

NL-OMON26668

Source
NTR

Brief title
BASTA-study

Health condition

Patients with dysphagia after esophagectomy with cervical anastomosis due to a benign anastomotic stricture.
Patienten met dysfagie na een buismaagreconstructie na slokdarmresectie met een cervicale anastomose veroorzaakt door een benigne anastomotische strictuur

Sponsors and support

Primary sponsor: Maag-, darm-, leverziekten UMC Utrecht
Source(s) of monetary or material Support: UMC Utrecht (investigator driven)

Intervention

Outcome measures

Primary outcome

Number of patients dysphagia free after 1 dilation in a period of 6 months (success rate).

Secondary outcome

1. Median number of dilation sessions after 6 months follow-up;

2. Time to repeat dilation;

3. Number of adverse events and serious adverse events;

4. Dysphagia will be evaluated using a validated questionnaire, the Mayo dysphagia Questionnaire (MDQ)41;

5. Quality of life: The effect of the treatment on general quality of life will be evaluated by the short form 36 (SF-35) health survey;

6. Patient's satisfaction with the administered therapy (scored by a visual analogue scale).

Study description

Background summary

Rationale: Dysphagia due to benign esophageal stricture formation can significantly impair quality of life. 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).
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 post-radiation, caustic or anastomotic strictures. These strictures are frequently refractory to dilation and require multiple (>5) sessions sometimes at weekly intervals.

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.
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 in abstract form) have compared (both mechanical and balloon) dilation 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. This was also the only study, in which a standardized technique and symptom scoring system was applied and blinding of patients and effect investigators was adequately performed. However, a trial including patients with anastomotic strictures alone has not yet been performed.

Objective: To compare Savary dilation with saline 0.9% injections (placebo) with Savary dilation with triamcinolon injections (80 mg) in patients with benign anastomotic esophageal strictures.

Study design: A multicenter double-blind, placebo controlled, randomized trial.

Study population: All patients with dysphagia grade 2-4 due to benign anastomotic strictures after esophagectomy with gastric tube and cervical anastomosis.

Intervention: Patients in treatment arm A will be treated with Savary Galliard dilation after four saline 0.9% injections of 0.5 ml and patients in treatment group B receive Savary dilation after four intralesional triamcinolon 0.5 ml injections 40 mg/ml in all four quadrants.

Main study parameters/endpoints:

1. Median time to repeat dilation ;

2. Success rate after 6 months follow-up (number of patients dysphagia free within 3 dilation sessions).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will be asked to fill in a questionnaire on their symptoms before first treatment, and patients will be contacted by phone after 1 week (for complications only) after 2 weeks, 1 month, three months and six months for another questionnaire. Furthermore,

patients will document their dysphagia score daily during the first month, thereafter; they will document their dysphagia score once weekly. No additional hospital visits or blood samples are required. The potential benefit expected in the study arm will be a longer dilation free interval and less dilation sessions to achieve relief of dysphagia.

Study objective

By injection of triamcinolone before dilation we hypothesise that the time to repeat dilation is increased and the total number of dilation sessions is decreased as well.

Study design

Follow-up at 1, and 2 weeks and 1, 3, and 6 months.

Intervention

Injection of placebo (saline 0.9%) vs injection of Kenacort (80mg) followed by Savaray dilation up to 16 mm.

Contacts

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Eligibility criteria

Inclusion criteria

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

2. Signed informed consent.

Exclusion criteria

1. Previous dilation;

2. Dysphagia due to (suspicion of) malignant tumour recurrence;

3. Patients unfit for upper endoscopy;

4. Active anastomotic leakage or infection;

5. Recent vaccination with '®alive' vaccine;

6. During the acute phase of viral, bacterial or fungal infections;

7. Known gastric or duodenal ulcera;

8. Previous allergic reaction to one of the substances of Kenacort;

9. A known infection with tropical worms (such as Strongyloide) or parasites;

10. Outpatient visit within 6 months at the treating endosocpist.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2010
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-03-2010
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	NL2119
NTR-old	NTR2236
Other	METC UMC Utrecht / CCMO : 09/319 / NL29249.041.09 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A