A RANDOMIZED COMPARISON OF DEGRADABLE ESOPHAGEAL STENT VS DILATION THERAPY: *DESTINY TRIAL* FOR PATIENTS WITH RECURRENT BENIGN ESOPHAGEAL STRICTURES

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To compare the efficacy and safety of dilation of recurrent benign esophageal strictures by using a degradable self-expanding stent or standard dilation therapy.

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

Summary

ID

NL-OMON35755

Source
ToetsingOnline

Brief title
DESTINY TRIAL

Condition

- Gastrointestinal stenosis and obstruction

Synonym
dysphagia, Recurrent benign esophageal strictures

Research involving
Human

Sponsors and support

Primary sponsor: William Cook Europe ApS
Source(s) of monetary or material Support: Cook Endoscopy USA

Intervention

Keyword: benign esophageal strictures, degradable stent, dilation therapy

Outcome measures

Primary outcome

Primary Objective:

- The number of repeat endoscopic dilations within 3 and 6 months after degradable esophageal self-expanding stent placement to standard dilation therapy in patients with benign recurrent esophageal strictures

Secondary outcome

Secondary Objectives:

- Safety, quality of life, direct medical costs and patient satisfaction after degradable esophageal self-expanding stent placement to standard dilation therapy during 12 months in patients with benign recurrent esophageal strictures

Study description

Background summary

Recurrent benign esophageal strictures are a regular cause of dysphagia and significantly impair quality of life. The treatment algorithm for patients with recurrent benign esophageal strictures, which is mostly based on experts* opinions, states that after failure of standard dilation, steroid injections can be added or electrocautery incisions can be performed. If strictures remain refractory (approximately 10% of patients), esophageal stent placement for prolonged dilation can be attempted. No randomized trials have been performed

to evaluate whether stent placement earlier in the treatment algorithm could be more effective and reduces the number of repeat dilations. Based on data of previously performed studies, it was hypothesized that patients with recurrent benign strictures may benefit from early stent placement.

Study objective

To compare the efficacy and safety of dilation of recurrent benign esophageal strictures by using a degradable self-expanding stent or standard dilation therapy.

Study design

International multicenter, randomized controlled trial conducted in the European Union

Intervention

Standard dilation therapy (balloon or bougie dilation) to 18 mm vs. placement of a degradable stent (SX-ELLA Stent Esophageal Degradable BD (Ella-CS, s.r.o., Czech Republic)) with a diameter of 18, 20, or 23 mm.

Study burden and risks

The potential benefit of study participation is the possibility for early stent placement, which implies a prolonged dilation period, earlier in the treatment algorithm than routinely performed. This may result in a longer dysphagia free period and a reduction of repeat endoscopies for patients with recurrent or refractory strictures, who would otherwise be frequently dilated. As it is currently not know whether this is indeed beneficial, the benefit of study participation is uncertain.

The risk associated with stent placement may be slightly higher as well, as retrosternal pain occurs more frequently after stent placement than after dilation therapy (15% vs. 0-5%). In most cases, pain is very well treated with analgesic and resolves within a week. Stent migration occurs in less than 10% of patients. In most of these cases, no interventions (such as stent removal) are required as the stent rapidly degrades, due to the low pH in the stomach. For patients being treated with bougie or balloon dilation, the risk of perforation is 0.5%. Perforation rate after BD stent placement is unknown, although a systematic review in a similar population has shown that perforations are rare (2%) when previous, rather stiff plastic stents designs were placed. This suggests that perforation rate after BD stent placement would at least be similar or lower than 2%. The risk of higher complication rates (5% vs. 15%) is considered justifiable due to the expected beneficial long term outcome in patients who receive BD stent placement. The number of repeat

endoscopies for repeat dilation, which is also considered a major burden to patients, will probably be significantly lower in the BD stent group.

The burden of study participation to patients consists of 8 follow-up phone calls taking approximately 15 minutes with a questionnaire and questions regarding dysphagia. BD stent patients will have one follow-up visit at 3 months that requires radiographic assessment. If the gold markers are seen at the 3 month assessment; then at 6 months, the patient will come back for another radiographic assessment. The questionnaire will also be completed during this visit. No additional study visits are necessary.

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

recurrent dysphagia for solid, semisolid, or liquid food after 1-5 previous dilations, due to a confirmed benign esophageal stricture.

Exclusion criteria

esophageal motility disorder, malignant stricture, previous stent placement and active leak, perforation or local infection.

Study design

Design

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):	19-01-2012
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	(bio)degradable esophageal stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-11-2011
Application type:	First submission
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
CCMO	NL36832.041.11