

Endoscopic BougieCap dilation for benign esophageal strictures: a feasibility study in daily practice

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27219

Source

Nationaal Trial Register

Brief title

BougieCap

Health condition

Benign esophageal stricture

Sponsors and support

Primary sponsor: Radboud university medical center

Source(s) of monetary or material Support: FMH Medical
Ovesco Endoscopy AG

Intervention

Outcome measures

Primary outcome

The main endpoint is the feasibility of EBD with the BougieCap dilator in patients with benign esophageal strictures. Feasibility is defined as:

- technical success of repeated EBD to 18mm with the BougieCap dilator according to standard practice for EBD

Secondary outcome

- Single EBD procedure time
- Total number of EBD procedures with the BougieCap dilator
- Recurrent dysphagia (Ogilvie 2-4) during follow-up of 12 weeks

Study description

Background summary

This multicenter non-randomized prospective observational cohort study will assess the feasibility of BougieCap dilation for patients with benign esophageal strictures. After dilation up to 18 mm, patients are followed up until 3 months and dysphagia scores, recurrent dysphagia and adverse events will be documented.

Study objective

In this study we aim to assess the feasibility in daily clinical practice of endoscopic BougieCap dilation for patients with a benign esophageal stricture.

Study design

Baseline: intervention (dilation up to 18 mm)

4 weeks: telephonic consultation

8 weeks: telephonic consultation

12 weeks: telephonic consultation

Incidental follow-up: BougieCap dilation for recurrent dysphagia

Intervention

Endoscopic dilation with the BougieCap dilator. In sequential dilation procedure the benign stricture will be dilated up to 18 mm.

BougieCap dilator: an endoscopic attachment cap intended to be used for dilating/expanding

esophageal strictures. The BougieCap is available in different diameters to perform incremental dilation (up to 6 mm) during a single procedure, identical to the conventional Savary bougie dilation. The standard endoscope plus BougieCap acts as a conventional Savary dilator, but with endoscopic view during dilation as the important extra feature.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

- Patients presenting with first episode of dysphagia due to benign esophageal stricture requiring repeated EBD to 18 mm
- Dysphagia due to benign esophageal stricture (e.g. post-surgery, radiation therapy, caustic ingestion, peptic, post-endothorapy)
- Dysphagia for solid, semisolid or liquid food (Ogilvie dysphagia score: 2-4)
- Written informed consent

Exclusion criteria

- Patient with a known eosinophilic esophagitis or motility disorder (e.g. achalasia)
- Patients with a known or suspected malignant esophageal stricture
- Patients with a benign stricture due to a previously performed laryngectomy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-02-2019
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion	
Date:	21-01-2019
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	NL7483

Register

NTR-old

Other

ID

NTR7725

: 2018-4530

Study results