

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON27219

### Source

NTR

### 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