

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

Gepubliceerd: 21-01-2019 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27219

Bron

Nationaal Trial Register

Verkorte titel

BougieCap

Aandoening

Benign esophageal stricture

Ondersteuning

Primaire sponsor: Radboud university medical center

Overige ondersteuning: FMH Medical

Ovesco Endoscopy AG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-02-2019
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	21-01-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7483

Register

NTR-old

Ander register

ID

NTR7725

: 2018-4530

Resultaten