Intensive endoscopic therapy versus standard treatment for untreated benign esophageal strictures resulting from excessive scar tissue formation after surgery

Gepubliceerd: 29-02-2016 Laatst bijgewerkt: 15-05-2024

We hypothesize that endoscopic combination therapy, including in- and excision of the stenotic fibrotic ring combined with steroid injections and bougie dilation, is more effective than standard repeated endoscopic bougie dilation.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29569

Bron
NTR

Verkorte titel
INCA

Aandoening

Benign esophageal strictures; Anastomotic strictures; Esophagectomy; Endoscopic dilation; Endoscopic incision

Benigne slokdarmstenosen; Naadstenosen; Slokdarmresectie; Endoscopische dilatatie; Endoscopische incisie

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Dysphagia-free period

Toelichting onderzoek

Achtergrond van het onderzoek

The study terminated due to lack of patient recruitment.

Doel van het onderzoek

We hypothesize that endoscopic combination therapy, including in- and excision of the stenotic fibrotic ring combined with steroid injections and bougie dilation, is more effective than standard repeated endoscopic bougie dilation.

Onderzoeksopzet

6 months of follow-up

Onderzoeksproduct en/of interventie

Intensive endoscopic therapy (=investigational treatment):

a) Endoscopic in- and excision of the stenotic fibrotic ring using a needle knife catheter.

b) Followed by injection of 0.5 ml aliquots Kenacort 40 mg/ml (= 20 mg of triamcinolone per injection) into 4 quadrants of the lesion.

c) Hereafter, the incised stricture is subsequently dilated up to 16 mm with bougienage. At the end of the procedure, the lesion is inspected endoscopically and pictures are taken.

d) The patient is scheduled for an additional endoscopic dilation procedure within approximately 1 week (range 5-9 days) during which the patient will be dilated up to a luminal diameter of 18 mm using bougie dilators.

Conventional, repeated endoscopic bougie dilation (= control group): Patients will be treated with endoscopic bougie dilation until a luminal diameter of 18 mm is reached. The endoscopic

procedures will be scheduled within approximately 1 week (range 5-9 days) following one another.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Untreated benign esophagogastric anastomotic stricture after esophagectomy.

- The stricture should be suitable for endoscopic incision:

a) Diagnosed at least 6 weeks after esophagectomy, and

b) Stricture length ≤ 1 cm.

- Dysphagia score ≥ 2.

- Age > 18 years.

- Written informed consent for study participation.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Benign esophageal stricture other than an esophagogastric anastomotic stricture.

- Strictures with a morphology unsuitable for needle-knife incision, such as long (> 1 cm), irregulair or tortuous strictures.

- Previous endoscopic treatment of the esophageal stricture, such as bougie/balloon dilation, steroid injection, incision therapy or stent placement.

- Previous stent placement post-esophagectomy for anastomotic leakage.

- (Suspicion of) recurrent or metastasized esophageal cancer.

- Persisting postoperative esophageal fistula.

- Inability to discontinue anticoagulants or high-dose antiplatelet drugs at time of the baseline procedure. Low-dose aspirin (max. 100 mg/day) may be continued.

- Known clotting disorder.

- Patients unable to provide written consent for the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland
Status: Werving tijdelijk gestopt

(Verwachte) startdatum:	01-09-2016
Aantal proefpersonen:	89
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	29-02-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42848
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5764
NTR-old	NTR6006
CCMO	NL57698.018.16
OMON	NL-OMON42848

Resultaten