PreCap-study

Gepubliceerd: 20-07-2015 Laatst bijgewerkt: 18-08-2022

Endoscopic resection of Barrett's neoplasia with the Captivator EMR device is effective and safe

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

Samenvatting

ID

NL-OMON23426

Bron
NTR

Verkorte titel
PreCap

Aandoening

Barrett's esophagus; early cancer; high grade dysplasia; endoscopic resection.

in Dutch: Barrett slokdarm, vroegkanker, hooggradige dysplasie, endoscopische resectie

Ondersteuning

Primaire sponsor: Academic Medial center Amsterdam, the Netherlands
Overige ondersteuning: Boston Scientific

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Phase I
1)Maximum diameter of the resection specimens retrieved with the CaptivatorTM -and DuetteTM devices.

Phase II
1)Percentage of successful endoscopic resection (i.e. resection of all lesion delineation markings)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Endoscopic resection (ER) is the core modality in endoscopic therapy for early esophageal neoplastic lesions (i.e. high grade dysplasia [HGD] or early carcinoma) in Barrett's esophagus (BE). Histopathological assessment of the resection specimen provides the opportunity to select patients suitable for further endoscopic treatment with additional ER or ablative therapy. Recently, a new MultiBand Mucosectomy (MBM) device (CaptivatorTM EMR, Boston Scientific Corporation, Natick, MA, USA) has been developed which may have advantages over the current MBM device (DuetteTM, Cook Medical, Limerick, Ireland) by improved visualization, passage of accessories, and suction power due to different trigger cords and cap.
Objective: The aim of this study is to assess the safety and efficacy of the new CaptivatorTM EMR device.

Study design: This study will be executed in two phases. Phase I of this study is a prospective randomized trial comparing the CaptivatorTM EMR and the DuetteTM MBM device for which 3-6 patients will be included; phase II is a prospective pilot series with the CaptivatorTM EMR for which 5 patients will be included.

Study population: For phase I adult male and female patients scheduled for esophagectomy will be included. For phase II adult male and female BE patients with known early esophageal neoplastic lesions scheduled for endoscopic resection will be included.

Intervention (if applicable): In phase I, ERs with the CaptivatorTM and DuetteTM device will be performed directly pre-esophagectomy in the upper healthy part of the esophagus. In phase II, all ERs will be performed with the CaptivatorTM EMR device instead of the DuetteTM device.

Main study endpoints: For phase I the primary outcome is the maximum diameter of the resection specimens retrieved with the CaptivatorTM EMR- and DuetteTM devices. For phase II the primary outcome is the percentage of successful endoscopic resections (i.e. resection of all lesion delineation markings).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In phase I, the additional risk with participation is related to the longer sedation time. Patients will not be exposed to significant device associated complications because all the study patients will directly undergo an esophagectomy after the ER procedure. In phase

II, patients will undergo a MBM procedure. Since the new CaptivatorTM EMR device is very similar to the current DuetteTM device, no additional risks for the MBM procedure are expected.

Doel van het onderzoek

Endoscopic resection of Barrett's neoplasia with the Captivator EMR device is effective and safe

Onderzoeksopzet

Phase I

Time 0: studyendoscopy prior to esophagectomy. After completion of studyendoscopy: end of study

Phase II

Time 0: treatment endoscopy

Time 2 (after 48 hours): telephone call

Onderzoeksproduct en/of interventie

Phase I:

Endoscopic resection with Captivator EMR device and with Duette EMR device (currently used EMR device) of esophageal tissue prior to esophagectomy

Phase II:

Endoscopic resection of Barrett's neoplasia with Captivator EMR device

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Phase I

1.Age 18-80 years

2.Subject is scheduled for esophagectomy

3.Subject is willing to participate, fully understands the content of the informed consent form, and signs the informed consent form.

Phase II

1.Age 18-80 years

2.Barrett’s esophagus with a visible abnormality and biopsy-proven high grade dysplasia and/or early cancer

3.Lesion with a maximum size of 4 cm in longitudinal length and 50% of the circumference.

4.No suspicion of submucosal invasion, based on the macroscopic appearance and/or endosonography

5.No signs of lymph node and/or distant metastasis on endosonography and CT-scanning of the thorax and abdomen.

6.Patient is scheduled for endoscopic resection of present BE neoplasia

7.Subject is willing to participate, fully understands the content of the informed consent form, and signs the informed consent form.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Phase I

1.Subject has previously undergone endoscopic therapy in the intended treatment zone, including (but not limited to) cryospray therapy, laser treatment, photodynamic therapy, endoscopic mucosal resection, radiofrequency ablation or argon plasma coagulation.

2.Presence of esophageal stenosis limiting access to the intended treatment zone.

3.Scarring by other causes of the intended treatment zone.

4.Subject refuses or is not able to provide written informed consent.

Phase II

1.Subject has previously undergone endoscopic therapy in the intended treatment zone, including (but not limited to) cryospray therapy, laser treatment, photodynamic therapy, endoscopic mucosal resection, radiofrequency ablation or argon plasma coagulation.

2.Presence of esophageal stenosis limiting access to the intended treatment zone.

3.Scarring by any cause of the intended treatment zone.

4.Subject refuses or is not able to provide written informed consent.

Onderzoeksopzet

Opzet

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

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	20-07-2015
Aantal proefpersonen:	11
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	20-07-2015
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	NL5146
NTR-old	NTR5286
Ander register	METC AMC : 2015_043

Resultaten

Samenvatting resultaten
Published in surgical endoscopy