Technical feasibility of the EsoFLIP Achalasia Dilation Balloon

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The objective of this study is to assess the technical feasibility of the EsoFLIP dilation balloon in the treatment of achalasia

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON38536

Source
ToetsingOnline

Brief title
EsoFLIP: Technical feasibility

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
motility disorder of the esophagus because of nerve degradation. Esophageal motility disorder and failure of LES relaxation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Bedrijf;Crospon ,Crospon

Intervention

Keyword: achalasia, esophagus, pneumatic dilation

Outcome measures

Primary outcome

Technical feasibility, defined as the percentage of successful dilations performed with this catheter.

Secondary outcome

Secondary endpoints: safety (adverse events and serious adverse events) efficacy, measurements of balloon diameter and pressure at different volumes of balloon inflation, the amount of mSV and the number of patients in which there is treatment failure.

Study description

Background summary

Achalasia is treated with medication, injection of botulism toxin, surgically by Heller myotomy or endoscopically by either *per-oral endoscopic myotomy* (POEM) or pneumatic balloon dilation. In the latter case, a balloon is inserted into the esophagus and dilated to a pressure of approximately 1.5 atm. Therapeutic success is approximately 90% for standard balloon dilation. Most balloons are calibrated to achieve a target diameter for a given balloon pressure in free air. It is however not necessarily the case that in-vivo the target diameter is achieved due to resistance/recoil from the esophagus. Fluoroscopy is often used to assess the lumen diameter post-dilation. This exposes the patient to radiation and does not give an actual lumen measurement (unless a prior calibration procedure is performed). With a new dilation catheter, the EsoFLIP, it is possible to measure the balloon diameter electronically during dilation. The EsoFLIP uses a commercially available impedance measurement technique with a series of measuring electrodes located within the dilation balloon. The balloon itself is a standard dilation balloon. With this technique, a digital image can be shown on a computer monitor, which accurately shows the shape of the balloon at that time. This obviates the need

for radiation exposure, since fluoroscopy will not be needed anymore.

Study objective

The objective of this study is to assess the technical feasibility of the EsoFLIP dilation balloon in the treatment of achalasia

Study design

Single arm prospective study with no comparator group. All patients will receive balloon dilation treatment according to standard clinical practice using a 30 mm EsoFLIP balloon. Two days later, treatment will be repeated using the 30mm catheter. Patients will be followed up afterwards for three months.

Intervention

Dilation of the LES using the EsoFLIP catheter.

Study burden and risks

Since pneumatic dilation is a well-established and well tested method for treating achalasia, it is well-known that there are certain risks to this treatment. The most important complications are perforation of the esophagus, a bleed in the esophagus, pain and the risk of developing gastro esophageal reflux disease. Since dilation with the EsoFLIP is comparable to standard dilation, we expect that the number and severity of complications will be either comparable or lower. Since this balloon gives feedback about its shape, it might be easier to estimate when the treatment is successful. Because of this, it is expected that there will be a reduction in the number of complications.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Between 18 and 70 years of age
-Diagnosed with achalasia by absence of peristalsis and impaired relaxation of the LES (during swallow-induced relaxation a residual pressure of >=10mmHg) on standard manometry
-Eckardt symptom score >3 at baseline
-Eligible for standard pneumatic balloon dilation therapy

Exclusion criteria

-Previous invasive treatment for achalasia
-Pseudoachalasia
-Megaesophagus (diameter of >=7 cm)
-Altered anatomy of the esophagus due to surgery
-Barrett*s epithelium (>M2; >C1) or any grade of dysplasia, seen during endoscopy or in a biopsy in the past six months
-A history of either suspected or confirmed esophageal cancer
-Confirmed eosinophilic esophagitis
-Liver cirrhosis, portal hypertension and/or esophageal varices
-Coagulopathy (INR>1.5, platelets<50.000/mm3) which has not been corrected prior to the procedure

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-07-2013
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Dilation balloon for the LES
Registration:	No

Ethics review

Approved WMO

Date:	15-05-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL43109.041.13