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Endoscopic treatment of anastomotic oesophageal stricture: a randomised study comparing initial dilation by electrocautery with Savary bougies with electrocautery

Submission date
11/04/2007

Recruitment status
No longer recruiting

Registration date
11/04/2007

Overall study status
Completed

Last Edited
20/01/2010

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR931

Study information

Scientific Title

Study objectives
Anastomotic strictures are common after oesophageal resection. These strictures often need multiple dilation procedures with Savary bougies, and some even fail despite many dilations. Based on the literature and our pilot study of electrocautery therapy of refractory benign oesophageal stenosis, electrocautery treatment is safe, and may provide an excellent alternative for primary treatment of oesophageal strictures.

A prospective randomised controlled trial is needed to compare dilation therapy with Savary bouginage with electrocautery therapy for the primary treatment of these strictures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the METC Erasmus MC on the 12th May 2004 (ref: MEC 238.671/2004/8).

Study design
Randomised controlled parallel group double blinded multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Anastomotic oesophageal stricture

Interventions
Patients will either undergo dilation with Savary bougies, or primary electrocautery.

An upper gastrointestinal endoscopy will be performed. The postoperative stenosis will be inspected and the diameter of the stenosis will be estimated by using the diameter of the endoscope (9.5 mm). These stenoses are usually located at 17 to 20 cm from the incisors.

For endoscopic bougie dilation of the stricture, a guide wire will be placed in the stomach, followed by removal of the endoscope and passage of Savary Gilliard bougies of increasing diameter over the guide wire according to standard procedures to a diameter of minimal of 16 mm and maximal 19 mm.

For endoscopic dilation of the strictures with electrocautery, the tip of the endoscope is positioned just proximal from the stenosis, and a needle knife catheter (Wilson Cook, Boston Scientific) is introduced through the working channel. Radial incisions are made in the stenotic ring with the needle knife catheter under direct visualisation. The required length of the cut is gauged according to the length of the stricture assumed by the endoscopist in the light of the membranous nature and the calibre of the stricture. The depth of the incision (estimated using the length of the needle knife as a comparator) is not deeper than 4 mm. The length of the incision is dosed to completely remove the rim of the stenosis.

In case of recurrent stenosis, dilation therapy will be repeated with the same modality as was used at baseline. Recurrent stenosis is defined as no passage or only passage with pressure of the endoscope (diameter 9.5 mm).

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
This study aims to compare the efficacy of Savary dilation versus endoscopic electrocautery treatment for the treatment of fibrotic anastomotic strictures after oesophageal resection.
1. The efficacy of therapy will be evaluated by means of objective and subjective criteria, which will be determined both before treatment and during follow-up after treatment
2. The objective criteria are obtained by standard items at endoscopy and body weight. Endoscopic evaluation of the stricture will take place at baseline, and will be repeated in case of recurrent or persistent symptoms
3. The European Organisation for Research and Treatment of Cancer (EORTC) health related Quality of Life Questionnaires, Short Form 36-question health survey (SF-36), Quality of Life Questionnaire on Cancer (QLQ C-30) (version 3) and Quality of Life Oesophageal Questionnaire (QLQ OES-18) are used to structure a quality of life questionnaire especially focused on benign oesophageal stenosis

All outcomes will be measured at zero, one, three and six months.

Secondary outcome measures
Is there a difference in the interval of retreatment between electrocautery and Savary bougies, because of stenosis of the anastomosis of the oesophagus?

All outcomes will be measured at zero, one, three and six months.

Overall study start date

17/06/2004

Completion date
01/09/2007

Eligibility

Key inclusion criteria
Sixty-two unselected consecutive patients with dysphagia due to a benign anastomotic stricture after transhiatal oesophagectomy with gastric tube reconstruction and cervical anastomosis will be included and randomised to either treatment arm. After informed consent, patients will either undergo dilation with Savary bougies, or primary electocautery.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
62

Key exclusion criteria
1. Oesophageal dilation with bougies or electrocautery is rarely contraindicated.
Patients should however not be dilated if they recently suffered from acute oesophageal perforation
2. Dilation is relatively contraindicated in the presence of:
2.1. a bleeding diathesis
2.2. severely compromised pulmonary function
2.3. severe or unstable cardiac disease, or in
2.4. patients with large thoracic aortic aneurysms

Date of first enrolment
17/06/2004

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
Netherlands

Study participating centre

Department of Gastroenterology and Hepatology
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Sponsor information

Organisation
Erasmus Medical Centre (The Netherlands)

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Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2009		Yes	No