

European Achalasia Trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26612

Source

NTR

Brief title

N/A

Intervention

Outcome measures

Primary outcome

1. Symptom control;
2. Therapeutic succes.

Secondary outcome

N/A

Study description

Background summary

Multi-center study; Subjects will be followed during several years, as long as possible. 1

month after treatment a manometry and an esophageal emptying will be performed and will be repeated every year. 1 year after treatment an endoscopy (+ Lugol staining) and 24h pH metry will be performed and will be repeated every 3 years.

Study objective

N/A

Study design

Every year.

Intervention

The major aim of this prospective, randomized, multi-center study is to compare the two treatments, namely pneumatic dilation and laparoscopic Heller myotomy.

Contacts

Public

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Eligibility criteria

Inclusion criteria

Between 18-75 yr of age, manometric diagnosis of achalasia, Eckardt score >3, signed informed consent.

Exclusion criteria

Severe cardio-pulmonary disease or other serious disease leading to unacceptable surgical risk, previous treatment except treatment with nitroderivatives, Ca++ channel blockers or sildenafil or dilation with Savary bougies or balloons of 2 cm diameter or smaller, pseudo-achalasia, mega-esophagus (> 7cm), previous esophageal or gastric surgery (except for gastric perforation), not capable to fill out questionnaires (f.e. due to language barrier), not available for follow-up, esophageal diverticula in the distal esophagus.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2003
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion	
Date:	02-06-2005
Application type:	First submission

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
NTR-new	NL17
NTR-old	NTR37
Other	: N/A
ISRCTN	ISRCTN56304564

Study results

Summary results

Pneumatic Dilation versus Laparoscopic

Heller's Myotomy for Idiopathic Achalasia

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