European achalasia trial: a prospective randomised multi-centre study comparing endoscopic pneumodilation and laparoscopic myotomy as treatment of idiopathic achalasia

Submission date	Recruitment status No longer recruiting	Prospectively registered		
04/08/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
04/08/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
30/11/2015	Digestive System			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr G E E Boeckxstaens

Contact details

Meibergdreef 9 Amsterdam Netherlands 1105 AZ +31 (0)20 566 7375 g.e.boeckxstaens@amc.uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

European achalasia trial: a prospective randomised multi-centre study comparing endoscopic pneumodilation and laparoscopic myotomy as treatment of idiopathic achalasia

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local ethics committee.

Study design

Randomised, active controlled, parallel group, multicentre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Achalasia

Interventions

Pneumatic dilation versus laparoscopic Heller myotomy.

Subjects will be followed during 10 years. 1 month after treatment a manometry and an oesophageal 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.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Symptom control
- 2. Therapeutic success

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/01/2003

Completion date

01/01/2013

Eligibility

Key inclusion criteria

- 1. Between 18 and 75 years of age
- 2. Manometric diagnosis of achalasia
- 3. Eckardt score greater than three
- 4. Signed informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

200

Key exclusion criteria

- 1. Severe cardio-pulmonary disease or other serious disease leading to unacceptable surgical risk
- 2. Previous treatment except treatment with nitroderivatives
- 3. Ca++ channel blockers or sildenafil or dilation with Savary bougies or balloons of 2 cm diameter or smaller
- 4. Pseudo-achalasia
- 5. Mega-oesophagus (greater than 7 cm)
- 6. Previous oesophageal or gastric surgery (except for gastric perforation)
- 7. Not capable of filling out questionnaires (i.e. due to language barrier)

- 8. Not available for follow-up
- 9. Oesophageal diverticula in the distal oesophagus

Date of first enrolment

01/01/2003

Date of final enrolment

01/01/2013

Locations

Countries of recruitment

Netherlands

Study participating centre

Meibergdreef 9

Amsterdam Netherlands 1105 AZ

Sponsor information

Organisation

Academic Medical Centre (AMC) (The Netherlands)

Sponsor details

Emma Kinderziekenhuis Postbus 22660 Amsterdam Netherlands 1105 AZ

Sponsor type

University/education

Website

http://www.amc.uva.nl/

ROR

https://ror.org/03t4gr691

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (The 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	12/05/2011		Yes	No
Results article	results	01/04/2013		Yes	No
Results article	results	01/05/2016		Yes	No