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

Submission date
04/08/2005

Registration date
04/08/2005

Last Edited
30/11/2015

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Digestive System

[_] 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

NTR37

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