ISRCTN05714772 https://doi.org/10.1186/ISRCTN05714772

Laparoscopic myotomy versus pneumatic dilatation for achalasia

Submission date	Recruitment status	[X] Prospectively registered
28/07/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/07/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/02/2019	Digestive System	

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
NCT00188344

Secondary identifying numbers
MCT-76449

Study information

Scientific Title
A randomised comparison of laparoscopic myotomy and pneumatic dilatation for achalasia

Study objectives
In patients with achalasia, is symptom relief at one year better with laparoscopic Heller myotomy with partial fundoplication, or pneumatic dilatation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Health Network Research Ethics Board, approval gained initially on May 19, 2005; renewed and continued approval until May 19, 2007 (reference number: 05-0065-A).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Achalasia

Interventions
Intervention Arm #1 (primary achalasia) will receive pneumatic dilatation
Intervention Arm #2 (primary achalasia) will receive Heller myotomy with partial fundoplication
Intervention Arm #3 (recurrent achalasia) will receive pneumatic dilatation
Intervention Arm #4 (recurrent achalasia) will receive Heller myotomy with partial fundoplication

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
The achalasia severity questionnaire score at 1 year.

Secondary outcome measures
1. Generic health related quality of life (SF-36)
2. Gastrointestinal disease-specific quality of life (GIQLI)
3. Measures of oesophageal physiology (lower oesophageal sphincter pressure, mean amplitude of oesophageal contractions, presence of any contractions after intervention)
4. Gastroesophageal reflux as measured by ambulatory 24-hour oesophageal pH measurement
5. Oesophageal emptying, as quantified by times barium oesophagram
6. Clinical outcomes of care including short term outcomes (i.e. death within 30 days of treatment); major complications (i.e. oesophageal perforation, prolonged hospitalisation, myocardial infarction etc.) and long-term clinical outcomes (i.e. survival after randomisation, incidence of oesophageal cancer, reintervention, clinical gastroesophageal reflux disease, use of antisecretory medications)

Overall study start date
01/08/2005

Completion date
31/08/2012

Eligibility

Key inclusion criteria
1. Persons of either sex age groups 18 and up
2. Clinical diagnosis of achalasia by a physician
3. Manometric diagnosis of achalasia including both: incomplete relaxation of the lower oesophageal sphincter during swallowing (<80% of elevation over intragastric pressure) and absence of oesophageal peristalsis (peristalsis in <20% of initiated contractions)
4. Facility with English, ability to complete English-language questionnaires

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria

1. Pseudoachalasia: oesophageal carcinoma; oesophageal stricture; previous oesophageal or gastric surgery; previous instrumentation of the lower oesophageal sphincter i.e. suture, polymer injection, silicone band
2. Previous gastric or oesophageal surgery: fundoplication; Heller myotomy; gastric resection; vagotomy with or without gastric drainage
3. Age 17 years or less
4. Pregnancy
5. Presence of severe comorbid illness: unstable angina; recent myocardial infarction (<6 months), cancer (except integumentary), unless free of disease for more than 5 years; end stage renal disease; previous stroke with cognitive, motor, speech, or swallowing deficit persisting longer than one month; severe respiratory disease; cognitive impairment

Date of first enrolment
01/08/2005

Date of final enrolment
31/08/2012

Locations

Countries of recruitment
Canada

Study participating centre
Toronto General Hospital
Toronto, Ontario
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Sponsor information

Organisation
University Health Network, Toronto (Canada)

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Sponsor type
University/education

Website

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ROR
https://ror.org/026pg9j08

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-76449)

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	01/11/2016		Yes	No