

Laparoscopic myotomy versus pneumatic dilatation for achalasia

Submission date 28/07/2005	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 28/07/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 15/02/2019	Condition category Digestive System	☐ 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

ClinicalTrials.gov (NCT)
NCT00188344

Protocol serial number
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).

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

The achalasia severity questionnaire score at 1 year.

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

Canada

M5G 2C4

Sponsor information

Organisation

University Health Network, Toronto (Canada)

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

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?
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[Results article](#)

results

01/11/2016

Yes

No