# Laparoscopic myotomy versus pneumatic dilatation for achalasia

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

### Plain English summary of protocol

Not provided at time of registration

### **Contact information**

### Type(s)

Scientific

#### Contact name

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#### Contact details

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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

### 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 Canada M5G 2C4

### Sponsor information

### Organisation

University Health Network, Toronto (Canada)

### Sponsor details

200 Elizabeth Street Toronto, Ontario Canada M5G 2C4 +1 416 340 4800 carolynm@uhnresearch.ca

### Sponsor type

University/education

#### Website

http://www.uhnresearch.ca

### 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