

A randomised controlled trial of Laparoscopic Nissen Fundoplication (LNF) versus omeprazole for treatment of patients with chronic Gastro-esophageal Reflux Disease (GERD)

Submission date 01/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 31/01/2019	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)

NCT00182260

Protocol serial number

Study information

Scientific Title

A randomized controlled trial of laparoscopic Nissen fundoplication versus proton pump inhibitors for the treatment of patients with chronic gastroesophageal reflux disease (GERD): 3-year outcomes.

Acronym

ELVIS (oEsophagitis - Laparoscopy Versus Inhibitors of Secretion)

Study objectives

1. Laparoscopic Nissen Fundoplication (LNF) is an effective intervention in the management of patients with chronic Gastro-oEsophageal Reflux Disease (GERD) requiring maintenance therapy
2. LNF is cost-effective compared with long-term medical therapy
3. LNF is more effective than maximum medical therapy in control of respiratory symptoms and complications of GERD

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from Research Ethics Board of St Joseph's Hospital on the 30th March 2000.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Gastro-Oesophageal Reflux Disease (GERD)

Interventions

Optimal medical therapy compared with anti reflux surgery - Laparoscopic Nissen Fundoplication (LNF).

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Omeprazole

Primary outcome(s)

GERD Symptom Scale and Symptom-free days

Key secondary outcome(s)

1. 24-hour pH
2. Economic analysis
3. Endoscopy
4. Oesophageal manometry
5. Health related quality of life (36-item Short Form health survey [SF-36])
6. Health Utility Index

Completion date

30/09/2007

Eligibility**Key inclusion criteria**

1. Male or female GERD patients aged 18 - 70 years with GERD symptoms
2. Prior long-term treatment with Proton Pump Inhibitors (PPI) with minimum duration of 1 year with expected future duration of at least 2 more years
3. Controlled on 20 - 40 mg/day maintenance PPI therapy prior to study, defined as GERD symptom score less than 25 and score of 70 or more on 1 - 100 Global Rating Scale at screening
4. Increase in GERD symptom score greater than or equal to 15 points at baseline (off omeprazole)
5. GERD symptom score greater than or equal to 25 at baseline (off omeprazole)
6. Percent acid reflux in 24 hour 24% at baseline off omeprazole
7. Positive Bernstein test at baseline
8. Willingness to adhere to randomised treatment with availability for 3 years of follow-up
9. Ability to answer self and interviewer-administered questions in English
10. Signed informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Aperistaltic oesophagus
2. Severe cardiac, respiratory, haematologic or other disease constituting an unacceptable surgical risk in the investigators opinion

3. Previous gastric, oesophageal or anti-reflux surgery
4. History of malignancy within the last year with the exception of basal cell carcinoma
5. Pregnancy or an intention to become pregnant in the following year

Date of first enrolment

01/01/2000

Date of final enrolment

30/09/2007

Locations

Countries of recruitment

Canada

Study participating centre

McMaster University

Hamilton, Ontario

Canada

L8N 4A6

Sponsor information

Organisation

McMaster University (Canada)

ROR

<https://ror.org/02fa3aq29>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-38147)

Funder Name

Ministry of Health and Long-Term Care (Canada) (Grant No.: 05276)

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?
Results article	economic evaluation results	01/03/2011	31/01/2019	Yes	No
Results article	results	01/08/2011	31/01/2019	Yes	No