A randomised controlled trial of Laparoscopic Nissen Fundoplication (LNF) versus omeprazole for treatment of patients with chronic GastrooEsophageal 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 [X] 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

Contact name

Dr Mehran Anvari

Contact details

McMaster University St. Joseph's Hospital Department of Surgery 50 Charlton Ave. East Hamilton, Ontario Canada L8N 4A6 +1 905 522 2951 anvari@univmail.cis.mcmaster.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00182260

Secondary identifying numbers

CIHR-MCT-38147; MOH Grant 05276

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

 Laparoscopic Nissen Fundoplication (LNF) is an effective intervention in the management of patients with chronic Gastro-oEsophageal Reflux Disease (GERD) requiring maintenance therapy
 LNF is cost-effective compared with long-term medical therapy
 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

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 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 measure GERD Symptom Scale and Symptom-free days

Secondary outcome measures

- 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

Overall study start date 01/01/2000

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants 216

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)

Sponsor details 1200 Main Street West Hamilton, Ontario Canada L8N 3Z5 +1 905 525 9140 hsresadm@mcmaster.ca

Sponsor type University/education

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

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