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

Submission date
01/09/2005

Recruitment status
No longer recruiting

Registration date
01/09/2005

Overall study status
Completed

Last Edited
31/01/2019

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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
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

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
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Hamilton, Ontario

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