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Does the LINX procedure achieve similar reflux control and improve postoperative symptoms, specifically gas bloating and inability to belch, when compared to laparoscopic fundoplication?

Submission date
28/05/2024

Recruitment status
Recruiting

Registration date
03/06/2024

Overall study status
Ongoing

Last Edited
05/06/2025

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Reflux disease, where stomach acid leaks up into the oesophagus (food pipe), can severely impact quality of life and lead to complications, including ulceration of the oesophagus. It is often controlled with self-help measures and medication. However, sometimes surgery is recommended. The current standard surgical treatment is called a fundoplication. This operation is carried out through keyhole (laparoscopic) surgery and tightens the lower oesophagus to prevent reflux. Fundoplication is very safe and improves the quality of life of most patients. However, many patients have gas bloating, difficulty swallowing and recurrence of their reflux symptoms.
As an alternative, some surgeons use a device called LINX and a keyhole procedure. LINX is a magnetic device that wraps around the lower oesophagus to prevent reflux. Studies suggest that LINX may cause fewer complications with a similar improvement in quality of life. However, there is a need for better evidence to compare LINX with fundoplication in the surgical treatment of reflux disease.

Who can participate?
Patients aged 18 years and above with gastro-oesophageal reflux disease that is insufficiently controlled by medical treatment or intolerance to medical treatment being considered for anti-reflux surgery

What does the study involve?
Patients will be randomly allocated to undergo either a laparoscopic LINX procedure or fundoplication. All participants will be followed up at 6 weeks, 6, 12 and 24 months to assess which treatment offers the best results after surgery. Quality of life, surgical complications, including the need for additional treatment, financial cost-effectiveness and the presence of acid that has refluxed into the lower oesophagus are all measured. A quality assurance programme within participating centres will ensure that procedures are completed to a high-quality standard. Study results will incorporate a patient and public involvement programme,

which will inform national and international guidelines for the surgical treatment of reflux disease.

What are the possible benefits and risks of participating?
The information from this study will help us understand whether the LINX procedure gives similar reflux control and improves symptoms after the operation, particularly gas bloating and not being able to burp, when compared to fundoplication at 24 months after surgery. At the moment this remains an unanswered question and this is why the researchers are doing this study.
Both fundoplication and the LINX procedure are well tolerated, but it is uncertain how common the side effects are with LINX compared to fundoplication - they could be similar, worse, or better; hence the need for this study to compare and find out. Both operations can result in gas bloating, difficulty belching and swallowing or an eventual recurrence of reflux symptoms after surgery and the need for reintervention or reoperation.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
July 2023 to June 2028

Who is funding the study?
NIHR Efficacy and Mechanism Evaluation (EME) Programme (UK)

Who is the main contact?
GOLF Trial Manager, golf@nds.ox.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
331404

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 58022, IRAS 331404

Study information

Scientific Title
Double-blind randomised controlled trial for treatment of Gastro-Oesophageal reflux disease; LINX management system vs Fundoplication (GOLF)

Acronym
GOLF

Study objectives
This study aims to determine whether the LINX procedure achieves similar reflux control and improves postoperative symptoms, specifically gas bloating and inability to belch when compared to fundoplication at 24 months after surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/05/2024, Wales REC6 (Floor 4, Institute of Life Science 2, Swansea University, Swansea, SA2 8PP, UK; Wales.REC6@wales.nhs.uk), ref: 24/WA/0154

Study design
Interventional; Design type: Treatment, Device, Surgery; Randomized

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Gastro-oesophageal reflux disease

Interventions
The GOLF study is a multi-centre, pragmatic, two-arm, double-blind, Phase III, randomized controlled trial (RCT). An embedded QuinteT Recruitment Intervention will be used to understand, monitor and address barriers to participation.

The study will recruit 460 patients (230 in each of two arms) recommended for anti-reflux surgery with gastro-oesophageal reflux disease (GORD) from at least 16 UK and 7 non-UK European large upper gastro-intestinal surgical centres. Patients will be randomized 1:1 to receive either a laparoscopic LINX procedure or fundoplication.

The primary outcome is the assessment of symptomatic GORD using the GORD-HRQL questionnaire at 24 months following surgery, and core secondary outcomes are the prevalence of inability to belch and gas bloating at 24 months also assessed by GORD-HRQL. Patients will be followed up either in clinic, via telephone or electronically at baseline, 6 weeks, 6, 12 and 24 months after surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
Symptomatic GORD and health-related quality of life (HRQL) assessed using the GORD-HRQL questionnaire at 24 months following surgery

Secondary outcome measures
1. Prevalence of gas bloating measured using participant-reported outcomes/GORD-HRQL and Foregut Symptom Questionnaire at 24 months postoperatively
2. Prevalence of inability to belch measured using participant-reported outcomes/GORD-HRQL and Foregut Symptom Questionnaire at 24 months postoperatively
3. Prevalence of symptomatic GORD, inability to belch and gas bloating measured using participant-reported outcomes/GORD-HRQL and Foregut Symptom Questionnaire at 6 weeks, 6 and 12 months after surgery
4. Severity of dysphagia and regurgitation measured using participant-reported outcomes /GORD-HRQL questionnaire at 6 weeks, 6, 12 and 24 months postoperatively
5. Global HRQL measured using participant-reported outcomes/EQ-5D-5L questionnaire at 6 weeks, 6, 12 and 24 months postoperatively
6. Utilisation of anti-GORD medications measured using participant-reported outcomes /questionnaire at 6 weeks, 6, 12 and 24 months postoperatively
7. 24-hour pH measurement measured using participant's medical records/24-hour pH measurement or BRAVO test at 12 months postoperatively
8. 30-day, 90-day, 12 and 24-month postoperative complication rates, including reoperation and endoscopic reintervention, measured using participant's medical records/postoperative outcomes
9. Cost-effectiveness of both treatments as measured by incremental cost per quality-adjusted life year (QALY) at 6 weeks, 6, 12 and 24 months postoperatively

Overall study start date
01/07/2023

Completion date
30/06/2028

Eligibility

Key inclusion criteria
1. Age 18 years and above
2. Willing and able to give informed consent
3. Patients with GORD insufficiently controlled by medical therapy or intolerance to medical therapy being considered for anti-reflux surgery
4. Symptomatic and objectively defined GORD; endoscopy with appearances or biopsies consistent with reflux oesophagitis, or 24-hour pH study or BRAVO test of the oesophagus consistent with GORD
5. No hiatal hernia or hiatal hernia <5 cm in length
6. Adequate lower oesophageal motility as defined by preoperative oesophageal manometry study. Oesophageal manometry will show a mean contractile amplitude of >30 mmHg or DCI >450 mmHg-s-cm in 70% of swallows.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 460; UK Sample Size: 460

Key exclusion criteria
1. Unsuitable for surgical intervention due to medical conditions precluding general anaesthesia
2. Suspected or known allergies to titanium, stainless steel, nickel, or ferrous materials
3. Previous anti-reflux or gastric surgery
4. Previous or planned neurosurgical intervention
5. Oesophageal manometry showing complete absence of lower oesophageal contractility

Date of first enrolment
30/06/2024

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester Royal Infirmary
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
James Cook University Hospital
James Cook University Hospital
Marton Road
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United Kingdom
TS4 3BW

Study participating centre

The Whittington Hospital
Highgate Hill
London
United Kingdom
N19 5NF

Study participating centre
Gloucestershire Royal Hospital
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Study participating centre
Heartlands Hospital
Bordesley Green East
Bordesley Green
Birmingham
United Kingdom
B9 5ST

Study participating centre
St Marys Hospital
St. Marys Hospital
Floyd Drive
Warrington
United Kingdom
WA2 8DB

Study participating centre
Southampton General Hospital
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
North Devon District Hospital
Raleigh Park
Barnstaple

United Kingdom
EX31 4JB

Study participating centre
St Thomas' Hospital
St. Thomas's Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Darent Valley Hospital
Darenth Wood Road
Dartford
United Kingdom
DA2 8DA

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Warwick Hospital
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
Churchill Hospital
Churchill Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Torbay Hospital
Torbay Hospital
Newton Road
Torquay
United Kingdom
TQ2 7AA

Study participating centre
Epsom and St Helier University Hospitals
St. Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre
Nottingham University Hospital
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Croydon University Hospital
London Road
Croydon
United Kingdom
CR7 7YE

Study participating centre
Russells Hall Hospital
Pensnett Road
Dudley
United Kingdom
DY1 2HQ

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Wexham Park Hospital
Wexham Street
Wexham
Slough
United Kingdom
SL2 4HL

Study participating centre
Frimley Park Hospital
Portsmouth Road
Frimley
Camberley
United Kingdom
GU16 7UJ

Study participating centre
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Great Maze Pond
London
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SE1 9RT

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Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR152268

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Trial results will be available on the trial website.

Intention to publish date
30/06/2028

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date