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	Recruitment status Recruiting	[X] Prospectively registered		
28/05/2024		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
03/06/2024 Last Edited	Ongoing Condition category	☐ Results		
		☐ Individual participant data		
14/11/2025	Digestive System	[X] Record updated in last yea		

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

Prof Sheraz Markar

ORCID ID

https://orcid.org/0000-0001-8650-2017

Contact details

Surgical Intervention Trials Unit (SITU)
University of Oxford
Botnar Research Centre
Nuffield Orthopaedic Centre
Old Road
Headington
Oxford
United Kingdom
OX3 7LD
+44 (0)7584 039433
sheraz.markar@nds.ox.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

331404

ClinicalTrials.gov (NCT)

NCT07093359

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Total final enrolment

0

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

United Kingdom

England

Study participating centre Manchester Royal Infirmary

Cobbett House Oxford Road Manchester England M13 9WL

Study participating centre Southmead Hospital

Southmead Road Westbury-on-trym Bristol England BS10 5NB

Study participating centre Queen Alexandra Hospital

Southwick Hill Road Cosham Portsmouth England PO6 3LY

Study participating centre James Cook University Hospital

James Cook University Hospital
James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre The Whittington Hospital

Highgate Hill

London England N19 5NF

Study participating centre Gloucestershire Royal Hospital

Great Western Road Gloucester England GL1 3NN

Study participating centre Heartlands Hospital

Bordesley Green East Bordesley Green Birmingham England B9 5ST

Study participating centre St Marys Hospital

St. Marys Hospital Floyd Drive Warrington England WA2 8DB

Study participating centre Southampton General Hospital

Southampton General Hospital Tremona Road Southampton England SO16 6YD

Study participating centre North Devon District Hospital

Raleigh Park Barnstaple England EX31 4JB

Study participating centre St Thomas' Hospital

St. Thomas's Hospital Westminster Bridge Road London England SE1 7EH

Study participating centre Darent Valley Hospital

Darenth Wood Road Dartford England DA2 8DA

Study participating centre Royal Derby Hospital

Uttoxeter Road Derby England DE22 3NE

Study participating centre Warwick Hospital

Lakin Road Warwick England CV34 5BW

Study participating centre Churchill Hospital

Churchill Hospital Old Road Headington Oxford England OX3 7LE

Study participating centre Royal Devon and Exeter Hospital

Royal Devon & Exeter Hospital Barrack Road Exeter England EX2 5DW

Study participating centre Torbay Hospital

Torbay Hospital Newton Road Torquay England TQ2 7AA

Study participating centre Epsom and St Helier University Hospitals

St. Helier Hospital Wrythe Lane Carshalton England SM5 1AA

Study participating centre Nottingham University Hospital

Nottingham University Hospital Derby Road Nottingham England NG7 2UH

Study participating centre Croydon University Hospital

London Road Croydon England CR7 7YE

Study participating centre

Russells Hall Hospital

Pensnett Road Dudley England DY1 2HQ

Study participating centre The James Cook University Hospital

Marton Road Middlesbrough England TS4 3BW

Study participating centre Wexham Park Hospital

Wexham Street Wexham Slough England SL2 4HL

Study participating centre Frimley Park Hospital

Portsmouth Road Frimley Camberley England GU16 7UJ

Study participating centre Guy's Hospital

Great Maze Pond London England SE1 9RT

Study participating centre Hillingdon Hospital

Hillingdon Hospital Pield Heath Road Uxbridge

Sponsor information

Organisation

University of Oxford

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>		12/07/2025	09/09/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes