

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

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<b>Registration date</b> 03/06/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/11/2025	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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](mailto:golf@nds.ox.ac.uk)

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Sheraz Markar

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# Additional identifiers

## ClinicalTrials.gov (NCT)

NCT07093359

## Integrated Research Application System (IRAS)

331404

## Central Portfolio Management System (CPMS)

58022

# 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  
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  
England  
UB8 3NN

**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?
<a href="#">Protocol article</a>		12/07/2025	09/09/2025	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes