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Body surface gastric mapping in patients with para-oesophageal hernias

Submission date
12/09/2025

Recruitment status
No longer recruiting

Registration date
23/09/2025

Overall study status
Completed

Last Edited
22/09/2025

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Para-oesophageal hernias are defined as the presence of the stomach and/or other abdominal organs or contents in the chest cavity, by abnormally passing through the natural orifice within the diaphragm (diaphragmatic hiatus) that normally only admits the gullet (oesophagus). There are different methods to measure how the stomach moves and empties food. Some tests are invasive, like using sensors inside the stomach during surgery, while others are less invasive, like breath tests. Recently, a new non-invasive technique called Body Surface Gastric Mapping (BSGM) has been developed. It uses special sensors placed on the skin over the stomach to measure its movements. BSGM has helped study stomach problems in conditions like diabetes, chronic stomach issues, and after major stomach surgeries. This study aims to see if BSGM can be used to understand how stomach function is affected in patients who have undergone a specific type of surgery to repair a hernia near the stomach. This could help improve our understanding of the effects of this surgery on stomach movement and function.

Who can participate?
Adult patients undergoing elective para-oesophageal hernia repair or giant para-oesophageal hernia (defined by herniation of more than 50% of the stomach into the chest).

What does the study involve?
Gastrointestinal (GI) symptoms are extremely common and are often experienced by people with giant para-oesophageal hernias. A giant para-oesophageal hernia happens when half or more of the stomach moves up into the chest through the opening in the diaphragm (the muscle that helps with breathing). GI symptoms before and after surgical repair of a giant para-oesophageal hernia can place a significant burden on a person’s quality of life, and the causes that drive such symptoms are poorly understood. Electrical activity monitoring in the stomach and gut offers an opportunity to better understand the reasons behind GI symptoms. It may help to gain new insight into the functioning of the digestive system. The purpose of this research is to study gut function and movement in those who have undergone giant para-oesophageal hernia repair surgery by measuring the electrical activity of the GI tract. The study may also provide new insights into the relationship between gut electrical activity and the symptoms people report.

What are the possible benefits and risks of participating?
This study is aimed at developing and testing a new tool for measuring the electrical activity of the digestive system in those with a giant para-oesophageal hernia. There are no direct benefits to the participants in the study. However, the findings of this study may clarify our understanding of why these symptoms are present in people with para-oesophageal hernias and ultimately how best to reduce such symptoms. The Gastric Alimetry recording device has no known risks to a participant's safety; however, wearing the device may cause some mild skin discomfort. Researchers will help adjust the device so that participants are comfortable throughout the recording process. Mild skin sensitivity could result from the skin prep used to attach the device or from the device itself. It is a painless and well-tolerated device, and previous use in other research projects has reported no serious cases of problems.

Where is the study run from?
Churchill Hospital, Oxford, UK

When is the study starting and how long is it expected to run for?
May 025 to October 2026

Who is funding the study?
Alimetry Ltd.

Who is the main contact?
Mr Richard Owen, Richard.Owen@ouh.nhs.uk

Contact information

Type(s)
Public, Scientific

Contact name
Dr Wing Kiu Chou

Contact details
Churchill Hospital, Old Rd, Headington
Oxford
United Kingdom
OX3 7LE
+44 (0)300 304 7777
kerry.chou@nhs.net

Type(s)
Principal investigator

Contact name
Mr Richard Owen

Contact details
Churchill Hospital, Old Rd, Headington
Oxford
United Kingdom
OX3 7LE

+44 (0)300 304 7777
Richard.Owen@ouh.nhs.uk

Additional identifiers

Integrated Research Application System (IRAS)
352689

Protocol serial number
PID18641

Study information

Scientific Title
A prospective pilot cohort study to investigate the utility and feasibility of using body surface gastric mapping (Gastric Alimetry) to assess gastric motility and function in patients who have undergone elective para-oesophageal hernia repair

Study objectives
To investigate the utility and feasibility of using Gastric Alimetry to assess gastric motility and function in patients before and after para- oesophageal hernia repair.

To correlate gastric motility and function (measured using Gastric Alimetry) with patient-reported outcomes (measured using POST and GORD-HRQL questionnaires) in patients who have undergone para-oesophageal hernia repair.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/09/2025, East Midlands - Leicester Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8118; leicestercentral.rec@hra.nhs.uk), ref: 25/EM/0182

Primary study design
Observational

Study design
Pilot prospective cohort study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Body surface gastric mapping in paraoesophageal hernia patients

Interventions
Gastric Alimetry testing pre-operatively and between 3-6 months post-operatively
The intervention in the current study is body surface gastric mapping (BSGM) measurement with the Alimetry device. BSGM will be used to provide insights into gut motility before and after

para-oesophageal hernia repair surgery. The aim of this is to correlate patient symptomology and BSGM results. Testing procedures will entail the application of an electrode array onto the abdomen of participants. The duration of testing will be around 4 hours, and participants will be asked to log their symptoms before, during and after the testing. Facilitation of testing will be done by clinical research fellows in an outpatient setting. This BSGM measurement will be performed once preoperatively and postoperatively.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Gastric Alimetry™

Primary outcome(s)
Ease and use of body surface gastric mapping device measured using patient self-reported questionnaires at any point pre-operatively and repeated 3 to 6 months post-operatively

Key secondary outcome(s)
Captured electrical activity data measured using data from the device correlated with patient-reported outcomes measured using a Patient Reported Outcome Score Test (POST) and the Gastroesophageal Reflux Disease-Health Related Quality of Life (GORD-HRQL) questionnaires at any point pre-operatively and repeated 3 to 6 months post-operatively.

Completion date
01/10/2026

Eligibility

Key inclusion criteria
1. Age over 18 years old
2. Elective para-oesophageal hernia repair (type of operation not specified)
3. Giant para-oesophageal hernia (defined by herniation of more than 50% of the stomach into the chest)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex

All

Key exclusion criteria
1. BMI greater than 35
2. Unable to provide informed consent
3. Had previous para-oesophageal hernia repair or oesophago-gastric surgery
4. Diagnosis of an oesophago-gastric cancer
5. Emergency para-oesophageal hernia at presentation/surgery
6. Skin allergy or extreme sensitivity to cosmetics or lotions

Date of first enrolment
01/12/2025

Date of final enrolment
01/08/2026

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Oxford University Hospitals NHS Trust

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Industry

Funder Name
Alimetry Ltd.

Results and Publications

Individual participant data (IPD) sharing plan
Access to data will only be available to those members included in the study protocol who are listed as co-investigators. Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

IPD sharing plan summary
Not expected to be made available