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# Are tests of oesophageal (food pipe) function useful and acceptable to patients with eosinophilic oesophagitis?

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|---|---|---|
| **Submission date**<br>08/09/2022 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>12/09/2022 | **Overall study status**<br>Completed | |
| **Last Edited**<br>31/10/2025 | **Condition category**<br>Digestive System | |

## Plain English summary of protocol

Background and study aims

This study aims to improve understanding of the symptoms of eosinophilic oesophagitis (EoE), an inflammatory condition of the oesophagus (food pipe). Tests will be used to see if the oesophagus is working properly and symptoms will be recorded, both before and after a course of treatment. This work will help understand why, despite treatment, a third of patients with EoE continue to have symptoms, making activities such as eating and staying nourished a challenge. EoE affects 10-40 per 100,000 people. This number is increasing, with EoE linked to allergies, triggered by environmental factors or foods. Symptoms include food sticking in the oesophagus. In serious cases, food needs removing during an emergency endoscopy/camera test. EoE is diagnosed if increased eosinophils (cells involved in allergic responses) are found in tissue samples taken during endoscopy. However, treatment currently only addresses whether eosinophils are controlled, not whether the oesophagus works properly.

Who can participate?

Patients aged 18 years or over at participating hospitals with a diagnosis of EoE

What does the study involve?

Two low-risk tests will be used to study the oesophagus in sixty adult patients with EoE. Manometry measures how the muscles in the oesophagus squeeze and clear swallowed material during eating. pH/impedance testing monitors inflammation in the oesophagus. Participants will have each test both before and after receiving treatment. The study will not influence treatment decisions or standard care. Both tests involve passing a thin tube through the nose into the oesophagus. Manometry takes about 20 minutes. pH/impedance testing involves the person going home with the tube (2 mm diameter) in place for 24 hours, with information recorded during quiet periods/sleep. Results will be studied to see how inflammation affects oesophagus muscle function, the passage of food and symptoms. 20 patients will be interviewed to explore how acceptable these tests are in monitoring EoE. This approach will help understand the feasibility of assessing EoE differently in the NHS, making steps towards improving quality of life for those affected.

What are the possible benefits and risks of participating?
Whilst individuals will not directly benefit from participation, major test results will be contextualised and therefore individuals may receive further information about their condition.

Where is the study run from?
Newcastle upon Tyne NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2021 to May 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Catherine Sykes, c.sykes1@newcastle.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Miss Catherine Sykes

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# Additional identifiers

### Integrated Research Application System (IRAS)
299013

# Study information

### Scientific Title
A mixed methods feasibility study into the use of physiological assessment in eosinophilic oesophagitis

### Acronym
SWALLeOeW

## Study objectives
Observational study to assess the use and acceptability of physiological investigations of oesophageal function in understanding symptoms in eosinophilic oesophagitis (EoE) and to assess the relationship between physiological parameters, symptom profiles and response to treatment.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 19/10/2022, London - Surrey Borders Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8104; surreyborders.rec@hra.nhs.uk), ref: 22/PR/1086

## Primary study design
Observational

## Study design
Dual-site exploratory mixed-method feasibility study comprising a serial diagnostic study with embedded qualitative design

## Study type(s)
Diagnostic

## Health condition(s) or problem(s) studied
Eosinophilic oesophagitis

## Interventions
High-resolution manometry (HRM) testing forms the initial part of this serial diagnostic study, assessing oesophageal function during eating in patients with EoE. Comparison will be made to diagnostic gold standards (water swallows) and patient-reported outcome measures (PROMs), using validated questionnaires for benign oesophageal motility disorders. HRM will be repeated following a treatment episode to assess for motility changes following treatment administered as part of standard care.

pH/impedance monitoring forms the second part of the study, evaluating the use of mucosal impedance measurements in monitoring EoE status before and after standard therapy, with patients undergoing tests directly following HRM. Mucosal impedance will be measured to assess its practicability as a marker of mucosal integrity during quiescent nocturnal periods.

Finally, a qualitative approach, using semi-structured interviews, will be used to explore themes surrounding the acceptability of tests to monitor disease status in individuals with EoE.

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)

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### Primary outcome(s)
1. Recruitment rate, recorded as the number of eligible participants who consent to participate in the study during the 21-month recruitment period
2. Attrition rate, assessed using the number of consented participants who do not remain in the study until the end of follow-up, defined as completing physiological assessments on visit 1 (single day) and where new medication is initiated, repeat investigations 2-4 months following this

### Key secondary outcome(s)
1. Swallowing parameters measured whilst participants eat a solid test meal using high-resolution manometry at visit 1/baseline (before any new treatment is instigated as part of routine clinical care) and at 2-4 months after a new treatment is instigated as part of routine clinical care where applicable
2. Temporal relationship between symptoms and swallowing parameters measured using high-resolution manometry during the solid test meal consumption both at visit 1/baseline and 2-4 months after a new treatment is instigated as part of routine clinical care where applicable
3. Mean nocturnal baseline impedance of the oesophageal mucosa measured using 24-hour ambulatory pH/impedance testing at visit 1/baseline (before a new treatment is instigated as part of routine clinical care) and at 2-4 months after a new treatment is instigated as part of routine clinical care where applicable
4. Gastro-oesophageal reflux exposure measured using 24-hour ambulatory pH/impedance testing at visit 1/baseline (before a new treatment is instigated as part of routine clinical care) and 2-4 months after a new treatment is instigated as part of routine clinical care where applicable
5. Dysphagia, reflux symptoms and oesophageal hypervigilance and anxiety measured using the Brief Esophageal Dysphagia Questionnaire, Reflux Disease Questionnaire and the Esophageal Hypervigilance and Anxiety Scale respectively, at visit 1 and 2-4 months after a new treatment is initiated (where applicable)
6. Routine markers of eosinophilic oesophagitis (e.g. histology, endoscopic appearances) measured as part of routine care will be compared to study findings from closest visits, e.g. baseline endoscopy compared to baseline tests and follow-up endoscopy 2-4 months after treatment initiation compared to follow-up tests

### Completion date
28/02/2026

## Eligibility

### Key inclusion criteria
1. Patients from County Durham and Darlington NHS Foundation Trust (CDDFT) or University College London Hospitals (UCLH)
2. Aged 18 years or over
3. New diagnosis of eosinophilic oesophagitis (>15/high-powered field (hpf) or 0.3 $mm^2$ on oesophageal biopsy and index oesophageal symptoms
4. Known diagnosis of eosinophilic oesophagitis (current histological and symptom status documented but does not impact inclusion)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Total final enrolment
51

### Key exclusion criteria
1. <18 years old
2. Current involvement in a Clinical Trial of an Investigational Medicinal Product (CTIMP) for eosinophilic oesophagitis (EoE)
3. Eosinophilia as a result of other known causes (local or systemic)
4. Oesophageal stricture on oesophagogastric duodenoscopy
5. Previous upper GI surgery
6. Active oesophageal comorbidity including Barrett's oesophagus, oesophageal varices, coagulation disorders
7. Significant nasopharyngeal pathology, preventing nasogastric intubation
8. Opiate use
9. Unable to provide informed consent
10. Limited verbal communication
11. Non English speaker

### Date of first enrolment
07/10/2022

### Date of final enrolment
31/08/2025

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**University Hospital of North Durham**
University Hospital of Durham
Dryburn Hospital
North Road

Durham
United Kingdom
DH1 5TW

**Study participating centre**
**University College London Hospital**
235 Euston Road
London
United Kingdom
NW1 2BU

**Study participating centre**
**Darlington Memorial Hospital**
Hollyhurst Road
Darlington
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DL3 6HX

# Sponsor information

**Organisation**
Newcastle upon Tyne Hospitals NHS Foundation Trust

**ROR**
https://ror.org/05p40t847

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health and Care Research

**Alternative Name(s)**
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon appropriate request at the end of the study period from Catherine Sykes (c.sykes1@newcastle.ac.uk). Written informed consent will be obtained for every participant regarding data use of this nature and any data shared would be anonymised prior to sharing. Data will be available for a minimum of 5 years.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Protocol file | version 1.1 | 05/10/2022 | 24/11/2022 | No | No |
| Protocol file | version 1.2 | 31/01/2024 | 01/03/2024 | No | No |
| Protocol file | version 1.3 | | 30/05/2024 | No | No |
| Protocol file | version 1.4 | | 31/10/2025 | No | No |
| Protocol file | version 1.5 | | 31/10/2025 | No | No |