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# Developing new tests to monitor patients with eosinophilic oesophagitis using capsule sponge instead of endoscopy

**Submission date**
08/02/2024

**Recruitment status**
Recruiting

**Registration date**
23/02/2024

**Overall study status**
Ongoing

**Last Edited**
23/01/2026

**Condition category**
Digestive System

[ ] 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
Eosinophilic oesophagitis (EoE) is a disease of the oesophagus ("food pipe") affecting tens of thousands of adults and children across the UK. Related to asthma, allergies and other chronic inflammatory conditions, this disease has been on the rise in recent years. However, it can often take years and even several trips to A&E due to food getting stuck in the oesophagus before a diagnosis is made. Treatments are available, but not all patients respond to treatment and the only way to check response is an invasive endoscopy. Finding the right treatment can take multiple endoscopies in a single year, and even after one is found a patient may need endoscopies throughout their life. This study aims to improve patient care in EoE in two ways: by decreasing the need for endoscopy through the use of minimally-invasive capsule sponge testing to collect cells from the oesophagus, and by providing a personalised predictive test for therapy response.

Who can participate?
Patients over 18 years old with EoE

What does the study involve?
Participants are offered both an endoscopy and a capsule sponge test. The resulting information will be clinically validated diagnoses alongside biomarker measurements, providing a clear readout for personalised EoE management.

What are the possible benefits and risks of participating?
This study is to assess if a simpler test, known as capsule sponge, can be used to regularly manage EoE instead of endoscopy. The capsule sponge test is:
1. Quick, the procedure only lasts for 10 minutes
2. Less invasive and does not require any sedation
3. A more comfortable experience (as stated by other patients)
4. Well-tested, more than 17,000 tests have been given to patients with no serious side effects
Disadvantages of taking part:
1. Participants may experience a mild sore throat for up to 24 hours and in some people, this

may last for a few days. Paracetamol and throat lozenges can be taken to help.
2. There is a very small risk (less than 1 in 2,000) of the sponge becoming detached from the thread, or the nurse is unable to remove it. If this happens, it will be easily removed during your endoscopy.
3. There is a very small risk that you may have some bleeding. If this happens, you will be assessed by your consultant and clinical nurse. This is unlikely to need any intervention but if required an endoscopy could be performed to find and stop the bleeding. This has never been needed in 10+ years of tests.

Where is the study run from?
Cyted Ltd (UK)

When is the study starting and how long is it expected to run for?
June 2023 to March 2026

Who is funding the study?
Innovate UK

Who is the main contact?
Samantha Roberts, samantha.roberts@cyted.ai

# Contact information

### Type(s)
Public

### Contact name
Ms Samantha Roberts

### Contact details
22 Station Road
Cambridge
United Kingdom
CB1 2JD
+44 (0)1480 453 437
samantha.roberts@cyted.ai

### Type(s)
Scientific, Principal investigator

### Contact name
Dr Sarah Killcoyne

### ORCID ID
https://orcid.org/0000-0003-3686-6167

### Contact details
22 Station Road
Cambridge
United Kingdom
CB1 2JD

+44 (0)1480 453 437
sarah.killcoyne@cyted.ai

# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
334862

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
IRAS 334862, CPMS 59420

# Study information

### Scientific Title
Quantitative biomarker identification for eosinophilic oesophagitis in non-endoscopic capsule sponge cell samples for monitoring treatment efficacy

### Acronym
QuBIE

### Study objectives
It is hypothesised that non-endoscopic capsule-based sponge cell collection will enable the identification of quantitative biomarkers for accurately monitoring the activity of disease in treated eosinophilic oesophagitis (EoE) patients.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 01/02/2024, North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8290; gmeast.rec@hra.nhs.uk), ref: 23/NW/0384

### Study design
Open-label parallel-arm cohort study

### Primary study design
Interventional

### Study type(s)
Diagnostic

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

### Interventions
Patients will be asked to undergo a capsule sponge test prior to a standard endoscopy with biopsy

### Intervention Type
Procedure/Surgery

### Primary outcome(s)
1. Eosinophil count in biopsy vs sponge pathology (number of eosinophils per high power field - standard measures in diagnosis) at time of procedure and for the sub-group at follow-up 8-12 weeks later
2. Biomarker quantification using ELISA assays for selected biomarkers at time of procedure and for the sub-group at follow-up 8-12 weeks later
3. Severity of symptoms measured using the Dysphagia Symptom Questionnaire (DSQ) at time of procedure and for the sub-group at follow-up 8-12 weeks later

### Key secondary outcome(s))
Patient satisfaction measured using survey at time of procedure and for the sub-group at follow-up 8-12 weeks later

### Completion date
31/03/2026

## Eligibility

### Key inclusion criteria
1. Over 18 years old with a histologically confirmed diagnosis of EoE
2. Male or Female
3. Newly diagnosed patients with EoE or known existing non-stenotic EoE patients who are on maintenance treatments (i.e., orodispersible budesonide, PPI, biologics, or dietary therapy) and monitoring
4. Patients currently enrolled in the CoSIE study (IRAS 314770) may be retrospectively included with consent

### 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. Age <18 years
2. Strictures or severe rings at most recent endoscopy that prevent passage of adult 9.8 mm gastroscope
3. Oesophageal dilatation within 24 months of clinic visit
4. Previous oesophageal perforation or surgical resection
5. Oesophagogastric malignancy
6. Oesophageal varices
7. Bolus obstruction since last endoscopy requiring hospital visit
8. Previous fundoplication or complicated hiatus hernia
9. Patient on warfarin with INR>=3

### Date of first enrolment
01/02/2024

### Date of final enrolment
31/03/2026

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**East and North Hertfordshire NHS Trust**
Lister Hospital
Coreys Mill Lane
Stevenage
England
SG1 4AB

### Study participating centre
**Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus**
Nottingham University Hospital
Derby Road
Nottingham
England
NG7 2UH

# Sponsor information

**Organisation**
Cyted Ltd

# Funder(s)

**Funder type**
Government

**Funder Name**
Innovate UK

**Alternative Name(s)**
UK Research and Innovation Innovate UK, innovateuk

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# 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? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |