ISRCTN14071734 https://doi.org/10.1186/ISRCTN14071734

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
28/02/2025

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 December 2025

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
http://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

EudraCT/CTIS number
Nil known

IRAS number
334862

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format please use contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
Patient satisfaction measured using survey at time of procedure and for the sub-group at follow-up 8-12 weeks later

Overall study start date
02/06/2023

Completion date
31/12/2025

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
200

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
31/10/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
East and North Hertfordshire NHS Trust
Lister Hospital
Coreys Mill Lane
Stevenage
United Kingdom
SG1 4AB

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

Study participating centre
County Durham and Darlington NHS Foundation Trust
Darlington Memorial Hospital
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Sponsor information

Organisation
Cyted Ltd

Sponsor details
22 Station Road
Cambridge
England
United Kingdom
CB1 2JD
+44 (0)1480 453 437
hello@cyted.ai

Sponsor type
Industry

Website
cyted.ai

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
innovateuk

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a clinical journal for gastroinestinal diseases upon completion of study.

Intention to publish date
01/01/2026

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date