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Developing new tests to detect oesophageal dysplasia in patients using historic capsule sponge data

Submission date 10/07/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/07/2024	**Overall study status** Ongoing	
Last Edited 13/11/2024	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims

Oesophageal cancer has seen a rapid rise in the U.K. since the 1990's with little improvement in the overall 5-year survival rate that continues to be less than 20%.

The pre-malignant tissue called Barrett's oesophagus provides an opportunity for early detection of cancer through monitoring of patients identified to have this condition.

Barrett's identification and monitoring presents additional complexities to the determination of risk. Only 0.3% of patients with a non-dysplastic Barrett's diagnosis will progress to an early cancer each year. Current clinical surveillance strategies for patients rely on regular endoscopic biopsies with histopathology, creating a significant burden on patients who are unlikely to develop cancer and specialists spend significant time and resources on each endoscopy. Despite this a Barrett's diagnosis is the best opportunity for early detection of this cancer.

Since 2020 patients at specific NHS sites in Scotland who were diagnosed with Barrett's have been offered an oesophageal capsule sponge test (i.e. Cytosponge™ or EndoSign®) for surveillance of previously non-dysplastic Barrett's. Patients with a positive test on the capsule sponge are recommended an urgent endoscopic investigation to look for dysplasia or early cancer. Patients with a negative test are recommended ongoing surveillance by capsule sponge or alternating endoscopy.

The Research & Development team at Cyted Health Ltd has developed novel molecular biomarker targets for diagnosis of Barrett's and dysplasia using a genomic methylation sequencing based approach. This offers a quantitative and objective diagnostic tool that will decrease the burden on histopathology by prioritising patients for investigation.

Who can participate?

Patients over 18 years old and previously diagnosed with Barrett's oesophagus

What does the study involve?

The NHS site will retrospectively consent patients who meet the criteria required and will share their endoscopy tissue blocks and data. The information will assist the Cyted health R&D team to develop a model that will provide a clear read out as to whether the patient has dysplasia or not.

What are the possible benefits and risks of participating?
This study is to validate a set of quantitative molecular biomarkers for detecting dysplasia or cancer using the capsule sponge test in patients known to have Barrett's oesophagus. This will allow patients in surveillance for Barrett's to be monitored using a less invasive test while ensuring that patients who show signs of early cancer to access endoscopic evaluation urgently. In this study, patients will only be asked to share follow-up endoscopic data to enable concordance measures to be evaluated between the molecular test and the gold standard of endoscopy with histopathology.
The primary risk of this project is the sharing of data and biopsy samples. Cyted Health Ltd uses secure systems, and pseudonymisation of all patient data to mitigate these risks.

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

When is the study starting and how long is it expected to run for?
March 2024 to September 2027

Who is funding the study?
Cyted Ltd (UK)

Who is the main contact?
Samantha Roberts, s.roberts@cytedhealth.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
334861

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 334861, CPMS 62342

Study information

Scientific Title
Biomarkers for detection of dysplastic Barrett’s oesophagus in retrospective capsule sponge samples

Acronym
DysplasiaBAR

Study objectives
It is hypothesised that non-endoscopic capsule-based sponge cell collection will enable the identification of quantitative biomarkers for accurately detecting dysplasia in patients

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/07/2024, East Midlands - Derby Research Ethics Committee (2 Redman Place, London, EC20 1JQ, United Kingdom; +44 207 1048 154; derby.rec@hra.nhs.uk), ref: 24/PR/0707

Study design
Single centre retrospective real-world observational study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Oesophageal dysplasia

Interventions
This study aims to collect endoscopic reporting for Barrett's patients who were previously tested using the capsule sponge and identified as having positive biomarkers for possible dysplasia. These endoscopic reports will be analysed alongside the prior capsule sponge results, and novel molecular biomarkers that will be identified in other capsule sponge cases to validate the use of novel molecular biomarkers to diagnose dysplasia in the capsule sponge.

Intervention Type
Other

Primary outcome(s)
Measured using patient records:
1. Capsule sponge biomarkers for dysplasia (p53/atypia)
2. Follow-up endoscopic histopathology for Barrett's oesophagus (non-dysplastic, indeterminate, low-grade, high-grade, intramucosal adenocarcinoma)

3. Novel whole-genome molecular targets (proprietary currently) evaluated using an algorithm to provide a probability estimation for likelihood of dysplasia/cancer.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/09/2027

Eligibility

Key inclusion criteria
Cases:
1. 18 years old or over
2. Male or Female
3. Previously diagnosed with Barrett's oesophagus
4. Capsule sponge test performed after 1 June 2021 with a positive p53 and/or positive atypia biomarker result
5. Endoscopic biopsy with pathology performed subsequent to capsule sponge

Controls:
1. 18 years old or over
2. Male or Female
3. Previously diagnosed with Barrett's oesophagus
4. Capsule sponge test performed after 1 January 2022 with a negative p53 and negative atypia biomarker result
5. Endoscopic biopsy with pathology performed subsequent to capsule sponge with non-dysplastic pathology observed

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
1. Under 18 years old
2. Barrett's diagnosis unconfirmed

3. Capsule sponge biomarker test missing p53 and atypia results
4. Missing endoscopic pathology results
5. Patient deceased

Date of first enrolment
20/09/2024

Date of final enrolment
31/05/2025

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road Glasgow
Glasgow
United Kingdom
G12 0XH

Sponsor information

Organisation
Cyted Ltd

Funder(s)

Funder type
Industry

Funder Name
Cyted Ltd

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet version 1.0	11/11/2025	11/11/2025	No	Yes
Protocol file		18/02/2024	15/07/2024	No	No