

# Barretts oesophagus screening trial in a case control study

<b>Submission date</b> 16/06/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/04/2017	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-study-to-see-how-well-a-new-way-screening-for-barretts-oesophagus-works-best2>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

A091986, Ethics reference - 10/H0308/71

## Study information

### Scientific Title

Evaluation of a non-endoscopic immunocytological device (Cytosponge) for Barretts oEsophagus Screening Trial in a case control study: BEST 2

## **Acronym**

BEST 2

## **Study objectives**

The purpose of the study is to obtain more accurate data on the potential of the Cytosponge as a screening modality (in conjunction with trifoil factor (TFF3) for Barrett's oesophagus (BE), and to find out its potential to determine the risk of cancer progression (in conjunction with biomarkers of risk).

The primary objectives of the study are:

1. Performance and safety characteristics of the Cytosponge test
2. Effectiveness of the Cytosponge for diagnosing BE compared with endoscopy, including specificity (from controls) and sensitivity (from cases).
3. For patients with BE, the ability of Cytosponge biomarkers to risk stratify patients, according to their future cancer risk, in comparison with the dysplasia grade obtained from endoscopic biopsies.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

National Research Ethics Services Cambridgeshire Research Ethics Committee, 25/10/2010, ref: 10/H0308/71

## **Study design**

Case control study

## **Primary study design**

Observational

## **Study type(s)**

Diagnostic

## **Health condition(s) or problem(s) studied**

Barrett's oesophagus

## **Interventions**

500-700 cases and 500-700 controls [a range is given because this will vary slightly depending on the prevalence of dysplastic cases in order to give us 100 cases of low grade dysplasia (LGD) and 100 high grade dysplasia (HGD)]. Any patient clinically fit for an endoscopy with Barretts oesophagus (for the cases) and (or) with upper GI symptoms of reflux or dyspepsia as an indication for endoscopy. Individuals must be able to provide informed consent.

A case control study design in which the cases will be patients with known Barretts oesophagus (BE) and controls individuals with reflux or indigestion (dyspepsia) symptoms referred for endoscopy. Four centres with expertise in Barretts oesophagus will recruit patients. All participants will swallow the Cytosponge device prior to having an endoscopy. The Cytosponge will be processed for a number of different biomarkers. The results will be compared with the endoscopy findings.

Statistical methods for proportions including estimation of proportions with confidence intervals and testing for difference between two proportions and trends in proportions.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

1. Performance and safety characteristics of the Cytosponge test
2. Effectiveness of the Cytosponge for diagnosing BE compared with endoscopy, including specificity (from controls) and sensitivity (from cases)
2. For patients with BE, the ability of Cytosponge biomarkers to risk stratify patients in comparison with dysplasia grade obtained from endoscopic biopsies

**Key secondary outcome(s)**

1. Differential sensitivity of screening BE with dysplasia (low and high grade) compared to non-dysplastic BE
2. Determine the reproducibility of the Cytosponge result by repeated testing in a subset of individuals
3. Logistics of high-throughput sample processing and automated analysis of Cytosponge specimens for use in routine National Health Services (NHS) or other health care settings.

**Completion date**

31/12/2016

**Eligibility****Key inclusion criteria**

1. Any participant 18 years and above clinically fit for an endoscopy with Barretts oesophagus (Cases) with or without upper gastrointestinal (GI) symptoms
2. Any participant 18 years and above clinically fit for an endoscopy with upper GI symptoms of reflux or dyspepsia as an indication for endoscopy / gastroscopy (Controls)
3. Ability to provide informed consent
4. Patients who have undergone endoscopic mucosal resection (EMR) for high grade dysplasia and due for repeat endoscopy

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Individuals with a diagnosis of an oro-pharynx, oesophageal or gastro-oesophageal tumour, or symptoms of dysphagia
2. Oesophageal varices, stricture or requiring dilatation of the oesophagus
3. On anticoagulation therapy / medication (warfarin, clopidogrel, heparin or tinzaparin)
4. Individuals who have had a myocardial infarction or any cardiac event less than six months ago
5. Individuals who have had a cerebrovascular event < 6 months ago where their swallowing has been affected
6. Patients who have had previous treatment such as photodynamic therapy (PDT) or radio frequency ablation (RFA)
7. Participants who are unable to provide informed consent
8. Participants under age 18
9. Participants who exclude beef from their diet as the gelatine is beef based. This can be discussed with the patient
10. Endoscopy is generally avoided in pregnant women and therefore it is unlikely that any pregnant women will be included although pregnancy would not be an absolute contraindication. Pregnancy / pregnancy test will not be recorded as part of the trial

**Date of first enrolment**

07/07/2011

**Date of final enrolment**

31/12/2016

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Hutchison/MRC Research Centre

Cambridge

United Kingdom

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**Sponsor information****Organisation**

Cambridge University Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/04v54gj93>

## Funder(s)

### Funder type

Charity

### Funder Name

Cancer Research UK (CRUK) (UK)

### Alternative Name(s)

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2017		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes