

# BEST3 - A trial of a new GP-based test for patients with heartburn symptoms

<b>Submission date</b> 16/01/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/01/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/02/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-the-cytosponge-test-in-gp-surgeries-for-people-with-heartburn-symptoms-best-3#undefined>

## Contact information

### Type(s)

Public

### Contact name

Ms Aisling Redmond

### Contact details

Cancer Research UK & King's College London Cancer Prevention Trials Unit  
Cancer Prevention Trials Unit (CPTU), Cancer Prevention Group  
School of Cancer & Pharmaceutical Sciences  
King's College London  
GH0603004 Research Oncology Seminar Room  
Floor 3, Bermondsey Wing  
Guy's Hospital  
Great Maze Pond  
London  
United Kingdom  
SE1 9RT  
+44 (0)207 882 2932  
amr75@MRC-CU.cam.ac.uk

## Additional identifiers

Central Portfolio Management System (CPMS)

32540

# Study information

## Scientific Title

Barrett's oESophagus Trial 3 (BEST3): randomised controlled trial comparing the Cytosponge™-TFF3 test with usual care to facilitate the diagnosis of oesophageal pre-cancer in primary care.

## Acronym

BEST3

## Study objectives

The aim of this study is to:

1. Demonstrate that the invitation to the Cytosponge-TFF3 test leads to an increase in the number of patients diagnosed with Barrett's oesophagus (BE) compared to the usual clinical care pathway in primary care
2. Gain an in-depth understanding of the health economics of the Cytosponge -TFF3 test in patients on long-term treatment with acid suppressants as well as the economics for the projected reduction of cancer-related deaths

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

East of England – Cambridge East REC, 21/12/2016, ref: 16/EE/0546

## Study design

Randomized; Interventional; Design type: Diagnosis, Device, Management of Care

## Primary study design

Interventional

## Study type(s)

Diagnostic

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

Specialty: Primary Care, Primary sub-specialty: Cancer; UKCRC code/ Disease: Oral and Gastrointestinal/ Diseases of oesophagus, stomach and duodenum, Cancer/ Malignant neoplasms of lip, oral cavity and pharynx

## Interventions

120 practices will be randomised on a 1:1 basis to either the intervention or control arm. Practices will be randomised via block randomisation and be stratified by number of eligible patients. A cluster randomisation will be used to simplify research procedures and minimise impact of differing clinical practice within the same practice.

Intervention arm: Participants on long-term acid suppressant medication will receive the Cytosponge™ -TFF3 test and a clinically-indicated endoscopy where required and followed up at 12 months.

Control arm: Participants will receive usual care and followed up at 12 months.

## **Intervention Type**

Other

## **Primary outcome(s)**

Effectiveness is assessed using GP and hospital records of histologically-confirmed Barrett's oesophagus at 12 months post GP recruitment.

## **Key secondary outcome(s)**

1. Cost-effectiveness is assessed using GP and hospital records to determine mean cost per patient receiving the Cytosponge™ -TFF3 test versus usual care and incremental cost per QALY gained of the Cytosponge™ TFF3 test versus usual care at 12 months post GP recruitment
2. Patient acceptability is measured using a bespoke questionnaire at 7-14 days post procedure
3. Accuracy is measured using Positive Predictive Value (PPV) and Negative Predictive Value (NPV) in relation to the length of BE at 12 months post GP recruitment
4. Safety is measured using number of adverse events reported by patients up to 7 days post procedure

## **Completion date**

01/09/2019

## **Eligibility**

### **Key inclusion criteria**

1. Aged 50 years and over
2. Records of at least 6 months of prescription for acid-suppressant medication in the last year

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

50 years

### **Sex**

All

### **Total final enrolment**

13514

### **Key exclusion criteria**

Current exclusion criteria as of 15/08/2017:

1. Recorded regular prescriptions of NSAIDs
2. Recorded upper GI endoscopy in the previous 5 years as identified from the practice database
3. Recorded diagnosis of a current or previous oro-pharynx, oesophageal or gastro-oesophageal tumour

4. Recorded diagnosis of Barrett's oEsophagus (BE)
5. Unable to attend the GP surgery
6. Deemed not fit enough by their GP

Previous exclusion criteria:

1. Recorded regular prescriptions of NSAIDs
2. Recorded regular prescription of Clopidogrel
3. Recorded upper GI endoscopy in the previous 5 years as identified from the practice database
4. Recorded diagnosis of a current or previous oro-pharynx, oesophageal or gastro-oesophageal tumour
5. Recorded diagnosis of Barrett's oEsophagus (BE)
6. Unable to attend the GP surgery
7. Deemed not fit enough by their GP

**Date of first enrolment**

15/03/2017

**Date of final enrolment**

01/05/2018

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Cancer Research UK & King's College London Cancer Prevention Trials Unit**

Cancer Prevention Trials Unit (CPTU), Cancer Prevention Group

School of Cancer & Pharmaceutical Sciences

King's College London

GH0603004 Research Oncology Seminar Room

Floor 3, Bermondsey Wing

Guy's Hospital

Great Maze Pond

London

United Kingdom

SE1 9RT

**Study participating centre**

**MRC Cancer Unit**

University of Cambridge

Box 197

Addenbrookes Hospital

Cambridge Biomedical Campus

Cambridge

United Kingdom  
CB2 0XZ

## Sponsor information

### Organisation

Cambridge University Hospitals NHS Foundation Trust and University of Cambridge

### ROR

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

## Funder(s)

### Funder type

Charity

### Funder Name

Cancer Research 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

Detailed datasets generated during the study for publication purposes will be available in the form of data supplements to the main journal publication and will be accessible as summary tables and analyses immediately upon publication. This may also include de-identified line-level participant data of a limited number of data fields to protect privacy. The full trial dataset is not expected to be made available due to data protection responsibilities and proprietary issues around data use.

### IPD sharing plan summary

Published as a supplement to the results publication

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/08/2020	04/08/2020	Yes	No
<a href="#">Results article</a>	secondary results: patient experience	10/01/2023	11/01/2023	Yes	No
<a href="#">Protocol article</a>	protocol	03/08/2018		Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Other publications</a>	Patient-reported experiences and views	07/04/2022	14/02/2024	Yes	No
<a href="#">Participant information sheet</a>		03/08/2018	14/02/2024	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes