ISRCTN68382401 https://doi.org/10.1186/ISRCTN68382401

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

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 16/01/2017 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 19/01/2017 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 14/02/2024 | Cancer | |

**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

**Study website**
https://www.best3trial.org/

## 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

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
GP practice

### Study type(s)
Diagnostic

### Participant information sheet
No participant information sheet available

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

### Secondary outcome measures
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

### Overall study start date
01/05/2016

### 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

### Age group

Adult

### Lower age limit
50 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 9000; UK Sample Size: 9000

### 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
England

United Kingdom

### 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

### Sponsor details
Addenbrookes Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ
+44 (0)1223 348490
Research@addenbrookes.nhs.uk

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/04v54gj93

## Funder(s)

### Funder type
Charity

### Funder Name
Cancer Research UK

### Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Other non-profit organizations

### Location
United Kingdom

## Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

### Intention to publish date
31/03/2020

### 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 proprietorial 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? |
|---|---|---|---|---|---|
| Protocol article | protocol | 03/08/2018 | | Yes | No |
| Results article | results | 01/08/2020 | 04/08/2020 | Yes | No |
| Results article | secondary results: patient experience | 10/01/2023 | 11/01/2023 | Yes | No |
| | | | 26/07 | | |

| | | | | | |
|---|---|---|---|---|---|
| HRA research summary | | | /2023 | No | No |
| Other publications | Patient-reported experiences and views | 07/04/2022 | 14/02 /2024 | Yes | No |
| Participant information sheet | | 03/08/2018 | 14/02 /2024 | No | Yes |