

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

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

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Additional identifiers

Protocol serial number

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

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Study participating centre

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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?
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
Protocol article	protocol	03/08/2018		Yes	No
HRA research summary			26/07/2023	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
Study website	Study website	11/11/2025	11/11/2025	No	Yes