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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
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

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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 hypothesis
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

Condition
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

Overall study end date
01/09/2019

Eligibility

Participant 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

Participant 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

Recruitment start date
15/03/2017

Recruitment end date
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
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Study participating centre
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Organisation
Cambridge University Hospitals NHS Foundation Trust and University of Cambridge

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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)
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