ISRCTN12730505 https://doi.org/10.1186/ISRCTN12730505

Barretts oesophagus screening trial in a case control study

Submission date	Recruitment status	[_] Prospectively registered
16/06/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/08/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/04/2017	Digestive System	

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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.

Overall study start date
07/07/2011

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 gastrintestinal (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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1000-1400

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, clopridogrel, 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
England

United Kingdom

Study participating centre
Hutchison/MRC Research Centre
Cambridge
United Kingdom
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Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

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, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2017		Yes	No