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Role of vinegar in identifying abnormal cells in Barrett's oesophagus

Submission date	Recruitment status	[ ] Prospectively registered
22/07/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/10/2015	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/05/2021	Digestive System	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-using-vinegar-find-changes-cells-people-barretts-oesophagus-abba

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19276

Study information

Scientific Title
A feasibility study with a crossover design to assess the diagnostic accuracy of acetic acid targeted biopsies versus non targeted biopsies (current practice) for detection of dysplasia during Barrett's surveillance: the ABBA study

Acronym
ABBA

Study objectives
Is a trial to investigate the diagnostic accuracy of acetic acid chromoendoscopy in a Barrett's surveillance population feasible and acceptable to patients and clinicians?

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=19276

Ethics approval required
Old ethics approval format

Ethics approval(s)
15/SC/0085

Study design
Feasibility study, including a multicentre randomised crossover diagnostic study and qualitative interviews

Primary study design
Interventional

Secondary study design
Randomised cross over trial

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
Topic: Cancer, Gastroenterology; Subtopic: Upper Gastro-Intestinal Cancer, Gastroenterology; Disease: Oesophagus, All Gastroenterology

Interventions
Participants will have two gastroscopies 4-10 weeks apart – one using mapping biopsies (current practice) and one using acetic acid. We will monitor how many agree to participate and reasons for withdrawal from the study. Numbers of precancerous areas detected by each method will inform how many patients we need for a larger study to test which method is best. We will explore participants' and doctors' views about acceptability of the new technique and how to improve study procedures using telephone interviews.

Intervention Type
Other

Primary outcome measure
1. To determine the feasibility of recruiting 200 Barrett's surveillance patients in 18 months
2. To assess participant acceptability of the study design through quantitative measures related to study procedures and in-depth qualitative feedback
3. To identify the degree of difference in dysplasia (pre-cancerous changes) detection rates between acetic acid gastroscopy (targeted biopsies) and standard gastroscopic practice (non-targeted mapping biopsies) to inform the power calculation for a definitive study
4. Feasibility of training and implementation of acetic acid guided dysplasia detection technique
5. To explore the acceptability to clinicians and patients of the concept of using a targeted biopsy technique for surveillance instead of non-targeted, mapping biopsies
6. To identify potential facilitators and barriers to recruitment and retention for the definitive trial
7. To describe adverse events for the two methods

Secondary outcome measures
1. To determine the feasibility of recruiting 200 Barrett's surveillance patients in 18 months
2. To assess participant acceptability of the study design through quantitative measures related to study procedures and in-depth qualitative feedback
3. To identify the degree of difference in dysplasia (pre-cancerous changes) detection rates between acetic acid gastroscopy (targeted biopsies) and standard gastroscopic practice (non-targeted mapping biopsies) to inform the power calculation for a definitive study
4. Feasibility of training and implementation of acetic acid guided dysplasia detection technique
5. To explore the acceptability to clinicians and patients of the concept of using a targeted biopsy technique for surveillance instead of non-targeted, mapping biopsies
6. To identify potential facilitators and barriers to recruitment and retention for the definitive trial
7. To describe adverse events for the two methods

Overall study start date
01/02/2015

Completion date
01/12/2017

Eligibility

Key inclusion criteria
1. Aged 18 years or above
2. Biopsy proven Barrett's metaplasia
3. At least 2cm of Barrett's metaplasia (C0 M2)
4. Willing and able to give informed consent

Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200

Total final enrolment
200

Key exclusion criteria
1. Less than 2cm (C0 M2) of Barrett's metaplasia
2. Significant oesophagitis
3. Known or prior oesophageal cancer
4. Known or prior oesophageal dysplasia (indefinite for dysplasia CAN be included)
5. Previous endoscopic therapy
6. Known allergy to acetic acid
7. Previous inclusion in the study

Date of first enrolment
01/05/2015

Date of final enrolment
01/11/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Gloucestershire Royal Hospital
United Kingdom
GL1 3NN

Study participating centre
Portsmouth Hospitals NHS Trust
United Kingdom
PO6 3LY

Study participating centre
Leicester Royal Infirmary
United Kingdom
LE1 5WW

Study participating centre
Brighton and Sussex University Hospitals
United Kingdom
BN2 5BE

Study participating centre
The Royal Bournemouth and Christchurch Hospitals
United Kingdom
BH7 7DW

Study participating centre
Western Sussex Hospitals
United Kingdom
BN11 2DH

Study participating centre
University of Portsmouth
United Kingdom
PO1 2FR

Sponsor information

Organisation
Portsmouth Hospitals NHS Trust

Sponsor details
Southwick Hill Road
Cosham
Portsmouth
England
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PO6 3LY

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility; Grant Codes: PB-PG-1013-32045

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		01/01/2020	10/05/2021	Yes	No

HRA research summary	28/06/2023	No	No