

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

Submission date 22/07/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/10/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/05/2021	Condition category Digestive System	<input type="checkbox"/> Individual participant data

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

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

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

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

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