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Dedicated Endoscopy for Barrett's Oesophagus (DEBO) compared to current Barrett's oesophagus surveillance endoscopy practice

Submission date
21/07/2020

Recruitment status
No longer recruiting

Registration date
12/08/2020

Overall study status
Completed

Last Edited
26/02/2024

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Barrett's oesophagus is a condition where the lining of the gullet (food pipe/oesophagus) changes in response to inflammation usually caused by heartburn (acid reflux). This is a common condition but, in some people the lining of the gullet can change further to become cancerous. To identify cases at a treatable stage, the British Society of Gastroenterology guideline advised patients with Barrett's oesophagus should have regular endoscopies (camera test down the gullet) every 2-5 years. This is known as surveillance. Currently, in the NHS, these tests are performed during a trained doctor or nurse endoscopy session. Within these sessions the endoscopist may see many different conditions and conduct different types of procedure.

This study aims to see if it would be beneficial or not to have a dedicated Barrett's endoscopy session conducted by a doctor or nurse with a specialist interest in that area. There has been no previous research to ascertain whether a dedicated list improves the quality of the endoscopy performed. To assess this, Barrett's oesophagus patients will be asked if they would be happy to be chosen at random to have their surveillance procedure during any endoscopy session (current normal practice) or on a dedicated Barrett's endoscopy session. Participants will be asked to complete a questionnaire about how they feel about their condition, the care they receive and their symptoms. Information will also be collected about the camera test and biopsy results to check how closely the care provided follows current best practice guidelines.

It is hoped that this pilot study will provide the basis to justify a larger study to look for differences between the two types of service.

Who can participate?
Any adult (aged over 18 years) patient who has a diagnosis of Barrett's oesophagus who comes for regular routine camera tests to monitor it and is able to understand the study and make decisions for themselves.

What does the study involve?
Eligible, interested participants will be invited to meet a member of the research team to discuss

the study and answer any questions about the study. If the participant is happy to be part of the study the researcher will explain the study and ask them to sign a consent form. Participants will then be chosen at random to have the surveillance procedure during any endoscopy session (current normal practice) or on a dedicated Barrett's endoscopy session. Participants will not be told which list they have been allocated to. This will help keep the study results accurate and fair, but the procedure will be similar to previous experiences of surveillance for participants.

Presently there is no evidence that either service is better for patients, however if participants have any concerns this can be discussed with the study team before consent to participate is given.

After the endoscopy test, participants will be provided with a questionnaire to complete at home about their condition, and the care that they have received. The study team will also collect information about the camera test and biopsy results. After the test and completion of the questionnaire participants will return to current normal care and study involvement is complete. The consent process for the study should only take around 10 to 20 minutes, the endoscopy will last a long as usual surveillance tests experienced by the participant, and the questionnaire takes about 30-60minutes to complete.

What are the possible benefits and risks of participating?
The study may not have a direct benefit to the participants but will help to understand of Barrett's oesophagus care pathways and support a larger study that may show one of these interventions improves the outcomes for Barrett's patients. Although no health risks are expected to be associated with this study, there is some possibility that slightly different techniques will be provided at the different endoscopy lists. However, all participants will be seen by a clinician qualified to perform the test. There is no proof yet that either list is better than the other.

Where is the study run from?
Salford Royal NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
From October 2019 to January 2023

Who is funding the study?
The National Institute for Health Research (NIHR) (UK) and Medtronic (UK)

Who is the main contact?
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Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
261043

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 45235, IRAS 261043

Study information

Scientific Title
A randomised controlled pilot trial comparing current Barrett's oesophagus surveillance endoscopy practice with a dedicated service

Acronym
DEBO pilot

Study objectives
A randomised controlled trial comparing a dedicated endoscopy service for Barrett's oesophagus versus current normal practice is feasible in the UK NHS hospital setting

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/06/2020, MREC Greater Manchester South (3rd Floor, Barlow House, 4 Minshull Street, HRA NRES Centre Manchester M1 3DZ; +44 (0)207 104 8010; gmsouth.rec@hra.nhs.uk)

Study design
Single-centre randomized controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
The dedicated service will be performed by an upper GI specialist consultant, nurse endoscopist, or clinical research fellow who has a specialist interest in the condition. This is defined by a self-declared interest and regular experience of performing Barrett's surveillance. The list should be scheduled appropriately and include only Barrett's patients. The non-dedicated lists are any other list performed by an endoscopist who is accredited by the Joint Advisory group to perform upper GI endoscopy who does not have a specialist interest in Barrett's and does not attend upper GI multidisciplinary meetings.

Patients who are known to have Barrett's oesophagus and who are due for their scheduled surveillance endoscopy will be found via booking department databases by the research nurses, chief investigator, principle investigator, or research fellow. They will be approached via sending

an invitation letter with a participant information sheet in the 6-8 weeks approaching their endoscopy. They will invited to meet one of the study team who will check their capacity and consent them for the study.

Once they have consented to be in the study they will be randomised by the clinical trials assistant with an envelope-assisted randomisation procedure to either the dedicated list or routine list. The participant will not be informed which list they have been allocated. Once randomised the participant will be allocated an endoscopy appointment by the endoscopy booking team with the endoscopists in both arms of the study blinded to the participants involvement in the study. Both study sites have an established dedicated service, hence it will be possible to blind the endoscopists in both arms. In hospitals with a dedicated service it is not uncommon for Barrett's surveillance to be allocated onto different endoscopy lists due to timing and availability therefore this closely reflects normal practice.

Once the endoscopy has been completed the research team will access the report and the biopsy results to find the data for the clinical outcome measures. The research team will input retrieved data onto an anonymised clinical reference form which is marked only with the participant's unique study number. The participant will be made aware that the study team will access this information during the written consent. Each participant will have one endoscopy only and this will be the endoscopy which is already planned in their surveillance programme.

The participants will be provided with a questionnaire after their endoscopy to complete at home with which they will be given a stamped addressed envelope for ease of return. They will be advised to complete it at home away from the endoscopy unit and to avoid confounding proximity to their endoscopy. The study will just look at the differences between the questionnaire outcomes, the endoscopy report documentation, and the biopsy results. The participant's ongoing follow-up and further surveillance will continue as normal after the study.

Added 10/01/2023:
Alongside the DEBO pilot a subsidy exploring clinician behaviours will run. This will involve interviewing clinicians about their experience of performing Barrett's surveillance using prompts based around the Theoretical Domains Framework of behaviour and interpreted using the COM-B model of behaviour change. This element of the study will involve interviews undertaken on Microsoft teams with telephone consent, and purposeful sampling used to recruit clinicians from a wide geographical and clinical background. Transcripts will be analysed using thematic analysis with a view to determine areas which could be focused on in terms of interventions to affect behaviour in future intervention trials. Recruitment will continue until thematic saturation is achieved this will likely be in the order of 10-20 participants.

Intervention Type
Procedure/Surgery

Primary outcome measure
Feasibility of a randomised controlled trial comparing a dedicated endoscopy service for Barrett's oesophagus versus current normal practice, measured using health-related quality of life questionnaire completed at 6 weeks post endoscopic surveillance and histological outcomes of endoscopy (no dysplasia, intestinal metaplasia, low-grade dysplasia, or high-grade dysplasia) measured at either the time of dedicated surveillance endoscopy session (intervention arm) or at normally scheduled endoscopy session (control arm)

Secondary outcome measures

There are no secondary outcome measures

Overall study start date
01/10/2019

Completion date
01/01/2023

Eligibility

Key inclusion criteria
1. Has the capacity to give informed consent
2. Aged >18 years old
3. Diagnosis of non-dysplastic Barrett's oesophagus

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

Key exclusion criteria
1. Previous diagnosis of precancerous changes
2. Unable to understand written English to a standard at which they can understand the questionnaire

Date of first enrolment
01/10/2020

Date of final enrolment
01/10/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salford Royal NHS Foundation Trust
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Study participating centre
Wrightington, Wigan and Leigh NHS Foundation Trust
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Sponsor type
Hospital/treatment centre

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ROR
https://ror.org/019j78370

Funder(s)

Funder type

Government

Funder Name
Medtronic

Alternative Name(s)
Medtronic Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal by October 2023.

Intention to publish date
31/10/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.1	18/11/2021	10/01/2023	No	No
Preprint results		29/11/2023	26/02/2024	No	No