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Quality of life measures in Barrett's Oesophagus care pathways

Submission date 11/09/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 01/11/2017	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 12/12/2022	**Condition category** Digestive System	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Barrett’s oesophagus is a condition where the cells lining the food pipe (oesophagus/gullet) have started to change. It is diagnosed when patients undergo a flexible camera test (endoscopy) of their gullet. It is a common condition mainly affecting patients with acid reflux symptoms. There is a small risk of the cells lining the oesophagus growing abnormally and becoming cancer (oesophageal cancer). Therefore, doctors currently recommend a camera test every 2-5 years. These tests don't prevent cancer, but should pick it up at an earlier more treatable stage. It is known that many conditions significantly reduce patient’s quality of life. It is suspected that patients with Barrett’s oesophagus also experience a reduction in their quality of life. It is uncertain whether this is due to their symptoms or worries and anxieties about getting cancer. Therefore this research intends to assess what impact Barrett’s oesophagus has on patients. This research will identify any particular problems patients experience and help us explore ways of improving their care. The aim of this study is to explore the patient’s viewpoint, finding out what they feel is important and how they would change their care.

Who can participate?
Adults aged 18 and older who suffer from acid reflux (heartburn), colonic polyps requiring surveillance, healthy individuals and those with Barrett’s oesophagus who have developed pre-cancer or cancer of the gullet.

What does the study involve?
Participants first complete a questionnaire given to them at one of their normal hospital appointments or via a postal invite. A small amount of participants will be invited to have a one on one interview. These interviews ask patients about how Barrett’s oesophagus impacts them and help us identify key changes to our follow up care (for example implementing a dedicated clinic for Barrett’s patients). Finally, after their surveillance endoscopy participants may be randomly assigned follow up to a dedicated Barrett’s clinic, a normal gastroenterology clinic or no clinic. These participants will complete one questionnaire after clinic or endoscopy and once again 4 to 6 months later.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating.

Where is the study run from?
This study is being conducted by NHS employed staff across three sites in the North West of England (Wrightington, Wigan and Leigh NHS Trust, Salford Royal Foundation Trust and Central Manchester University Hospitals).

When is the study starting and how long is it expected to run for?
February 2015 to February 2021

Who is funding the study?
Medtronic Europe S.a.r.l. (EU)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
34114

Study information

Scientific Title
Assessing the patient impact and burden of current care pathways in Barrett’s Oesophagus

Acronym
BOBO

Study objectives

1.To assess the impact of Barrett's Oesophagus and its care pathways from the patient's perspective
1.1. Assess Health Related Quality of Life (HRQOL) in Barrett's Oesophagus patients undergoing surveillance (quantitative methodologies)
1.2. Identify patient's follow up needs and evaluate the potential burden of Barrett's Oesophagus (qualitative methodologies)
2. To explore potential modifiable factors associated with impaired HRQOL in Barrett's Oesophagus.
2.1. Assessing the effectiveness and practicalities of a, patient designed, follow up intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Yorkshire and Humber-Sheffield Research Ethics Committee, 15/02/2016, ref: 16/YH/0035

Study design
Non-randomised; Both; Design type: Process of Care, Education or Self-Management, Complex Intervention, Active Monitoring, Cohort study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Gastroenterology, Primary sub-specialty: Gastroenterology; UKCRC code/ Disease: Oral and Gastrointestinal/ Diseases of oesophagus, stomach and duodenum

Interventions
This clinical research will be divided into 3 sections for the purposes of data collection and analysis:

1. Assessing Health Related Quality of Life in Barrett's Oesophagus (Cohort Study).
This quantitative research will involve a one-off questionnaire evaluating HRQOL and other potentially significant factors. BO patients currently enrolled in surveillance will be invited to take part. The BO cohort will be compared to age, sex, co-morbidity and population matched control groups (alternatively these confounding factors may be accounted for in the analysis);
-Normal healthy individuals. (1 questionnaire)
-Gastroesophageal Reflux Disease without BO. (1 questionnaire)
-Colonic adenoma surveillance. (1 questionnaire)
-BO with dysplasia or early Oesophageal adenocarcinoma (OAC). Due to increased cancer conversion rates associated with dysplastic BO (low grade and high grade dysplasia), current care pathways in the UK recommend endoscopic therapy (ET). After ET patients undergo a more intensive surveillance regime (Fitzgerald et al. 2013). Patients with BO and early OAC which is deemed amenable to ET will also be included, considering their endoscopic treatment and subsequent surveillance is comparable to that of dysplastic BO. The impact of these diagnoses, treatment pathways and subsequent heightened surveillance on patients HRQOL is poorly understood. A prospective assessment of these patients will occur at diagnosis (before ET) and again between 4 and 12 months later (after ET) (2 questionnaires in total). In order to provide a

greater understanding of the effects of this treatment pathway and ensure adequate numbers patients who are already post ET will be recruited. This will be a one-off assessment of HRQOL (1 questionnaire).

2. Identifying patients follow up needs and burden of Barrett's Oesophagus (Qualitative Study)
The second element of this research aims to supplement the quantitative data gathered in section 1.1 and explore ways of improving follow up care for BO patients. Semi structured in-depth interviews with non-dysplastic BO patients undergoing surveillance will be conducted. This research will inform the development of a follow up intervention aimed to improve the patient journey. This may be in the form of a dedicated BO clinic, direct access line or virtual clinic for example.
Qualitative Methodologies will be used to obtain a more in depth view of patients concerns and ideas. All participants will be enrolled in BO surveillance at a single NHS District General Hospital. Participants will be recruited to represent differing ages, gender and disease duration. All participants will then undertake a semi structured in-depth one to one interview. Data collection will continue using theoretical sampling (Glaser & Strauss 1967) until thematic saturation is reached with maximum participant variation. Typically, this occurs between 15-25 interviews. All interviews will be audio recorded, transcribed verbatim and anonymised prior to analysis.

3. Are factors associated with reduced QOL modifiable? (A randomised prospective intervention pilot study)
This, proof of principal, randomised prospective intervention study will assess the practicalities and potential efficacy of a patient orientated follow up intervention (designed in section 1.2). All patients, able to give informed written consent, currently undergoing BO surveillance will be eligible to take part. We have chosen not to recruit new diagnoses for this study as ethically it would be inappropriate to randomise patients to solely endoscopic follow up
Participants will be recruited at the time of their latest surveillance endoscopy. They will then be randomised, by a participant independent of the trial team, to one of three groups
-Continued endoscopic surveillance only
-Continued endoscopic surveillance plus follow up intervention (likely to be in the form of a specialist BO clinic)
-Continued endoscopic surveillance plus general gastroenterology clinic follow up

Intervention Type
Other

Primary outcome(s)
1. Health related quality of life is measured using a self-administered questionnaire as a one off assessment in all groups and at baseline and between 4-12 months in the Barrett's oesophagus with dysplasia group.
2. Follow up needs and patient burdens are measured using semi-structured in-depth patient interviews
2.1 Health related quality of life is measured using a self-administered questionnaire after intervention (clinic arms), after endoscopy (non-clinic arm) and then 4 and 6 months later (all arms)

Key secondary outcome(s))
There are no secondary outcome measures.

Completion date

01/03/2023

Eligibility

Key inclusion criteria
1. Must have capacity to give informed consent
2. >18 years old. No upper age limit.
3. Male or Female
4. Meet the diagnostic criteria for each group
4.1. Non-Dysplastic Barrett's Oesophagus. All patients enrolled in surveillance who have been given a diagnosis of BO irrespective of current histology (lack of intestinal metaplasia on latest biopsies is not a criterion for exclusion providing future surveillance is indicated/recommended)
4.2. Barrett's oesophagus with dysplasia or early oesophageal adenocarcinoma. Any patient with BO diagnosed with low grade dysplasia, high grade dysplasia or early OAC eligible for ET.
4.3. Colonic Polyps. Participants currently undergoing endoscopic surveillance for colonic polyps
4.4. Gastro-oesophageal reflux disease. Participants without BO who have been diagnosed with any of the following; "gastroesophageal reflux + oesophagitis", "gastroesophageal reflux – oesophagitis", "gastroesophageal reflux disease", "GORD", "acid reflux" or "heartburn", "dyspepsia".
4.5. Normal Healthy Individuals. Population control participants who do not exhibit significant co-morbidities

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Lack capacity to consent
2. <18 years old

Date of first enrolment
01/01/2018

Date of final enrolment
31/10/2018

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Leigh Infirmary
Wigan, Wrightington and Leigh NHS Trust
Leigh Endoscopy Department
The Avenue
Hanover Building
Leigh
United Kingdom
WN7 1HS

Study participating centre
Royal Albert Edward Infirmary
Wigan, Wrightington and Leigh NHS Trust
Wigan Lane
Wigan
United Kingdom
WN1 2NN

Study participating centre
Salford Royal NHS Foundation Trust
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Manchester Royal Infirmary
Endoscopy Department
Oxford Road
Manchester
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M13 9WL

Sponsor information

Organisation

Wrightington, Wigan And Leigh NHS Foundation Trust

ROR
https://ror.org/028mrxf52

Funder(s)

Funder type
Government

Funder Name
Medtronic Europe S.a.r.l.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2017	09/11/2020	Yes	No
Results article	results	01/02/2019	09/11/2020	Yes	No
Results article	results	01/04/2019	09/11/2020	Yes	No
Results article	results	31/03/2020	09/11/2020	Yes	No
HRA research summary			28/06/2023	No	No