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National root cause analysis to lower missed diagnoses of oesophageal and gastric cancers

Submission date
18/04/2023

Recruitment status
No longer recruiting

Registration date
06/06/2023

Overall study status
Ongoing

Last Edited
14/03/2024

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
The are 15,800 people in the UK diagnosed with oesophageal or stomach cancer annually. Around 8% (approximately 1200 per year) had an endoscopy that did not find their cancer in the three years before diagnosis. This is known as post-endoscopy upper gastrointestinal cancer or 'missed' cancer. Missing cancers is bad, as the earlier they are identified, the more treatable they are and the better the outcome. This research is needed to find out why cancer is missed at endoscopy, tackle differences between hospitals and reduce missed cancers. The second highest endoscopy research priority for the British Society of Gastroenterology is "How can we improve the quality of upper gastrointestinal endoscopy?". The rate of missed cancer endoscopy is the most important endoscopy quality measure. The study aims to find out why cancer may not be found during endoscopy (flexible telescope examination of the oesophagus (gullet) and stomach), to reduce the risk in future.

Who can participate?
All endoscopy providers in the English NHS

What does the study involve?
Developed with the assistance of the Research Design Service. The study team have experience using routine NHS data to identify missed cancers that occurred in the past. However, to make a difference in endoscopy now, it is necessary to identify and investigate missed cancers as soon as possible after they occur.

This project will:
1. Adapt methods previously successfully used to identify and investigate missed bowel cancers. When a new potentially missed oesophageal or stomach cancer is found, the hospital will be informed who did the endoscopy and they will be asked to review the records in detail to understand why it was missed (root cause analysis).
2. Pool the results of these detailed analyses of missed cancers nationally to understand the common reasons for cancers being missed. Use these results to get the NHS to take steps to limit missing cancers in future.

What are the possible benefits and risks of participating?
The benefits of enrolment in the root cause analysis system are many. Data gained from this study will identify risk factors associated with missing cancer on endoscopy and improve endoscopy unit practice in the future with targeted interventions. There are no risks to participation in the study.

Patient and public involvement
Mimi McCord, chair of Heartburn Cancer UK (co-applicant and co-author of this summary) commented “It is imperative that an accurate diagnosis is achieved at the first endoscopy. Early diagnosis is vital to achieve a good outcome and possible cure with a cancer that has an appalling prognosis.”

Heartburn Cancer UK, Action Against Heartburn and the Oxfordshire Oesophageal and Stomach Organisation fully support this project and have contributed to the study design, particularly around, as far as possible, having a “no blame” approach, and being open with patients when cancer is found to be missed.

Where is the study run from?
Sandwell & West Birmingham Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
September 2022 to April 2026

Who is funding the study?
Research for Patient Benefit Programme (RfPB), National Institute for Health and Care Research (NIHR): NIHR203599 (UK)

Who is the main contact?
Dr Nigel Trudgill, Nigel.trudgill@nhs.net (UK)

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
328295

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 56102, IRAS 328295

Study information

Scientific Title

Reducing the rate of missed diagnoses of oesophageal and gastric cancers during endoscopy through endoscopy provider root cause analysis of potentially missed cancers

Study objectives
Observational database study with a hypothesis that the creation of a national root cause analysis system for missed upper gastrointestinal (GI) cancers would identify common risk factors for missing upper GI cancer during endoscopy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/06/2023, North West - Preston Research Ethics Committee (postal address: not provided; +44 (0)207 104 8364, +44 (0)207 104 8156, +44 (0)207 104 8181; preston.rec@hra.nhs.uk), ref: 23/NW/0193

Study design
Diagnosis process of care education or self-management cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Medical and other records

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
Upper gastrointestinal cancer

Interventions
The project will be composed of five interlinked work packages. These are:

1. Identification of all PEUGIC in the English NHS
Following appropriate ethics and information governance approvals with NHS Digital, including producing a data protection impact assessment to support data flows, the research team will adapt a previously developed algorithm to identify post-colonoscopy colorectal cancer using routine cancer and endoscopy data across the NHS. This will be adapted to identify PEUGIC cases prospectively. Essentially, the linkage of almost real-time Hospital Episode Statistics (for endoscopy) and National Cancer Registration and Analysis Service (NCRAS) databases every quarter will enable the identification of patients with oesophageal and stomach cancer who have had an endoscopy in the previous 6-36 months, where that cancer was not detected at the

endoscopy and will be classed as a PEUGIC. The service in which the endoscopy was performed will be responsible for capturing details of cancer and other relevant factors about the PEUGIC and transferring them to the root cause analysis tool described in work package 2.

2. Development of a secure web-based root cause analysis tool
Based on the national root cause analysis tool for post-colonoscopy colorectal cancer, a proforma will be developed that captures the data items required to undertake a comprehensive root cause analysis of a PEUGIC involving the following areas:

1. Patient – Demographic details
2. Endoscopy – Details of the procedure itself
3. Cancer – Nature of the missed cancer treatment
4. Management – plan following the endoscopy
5. Summary – PEUGIC classification, the potential to be avoidable, the duty of candour

We have learned from our current work on post-colonoscopy colorectal cancer root cause analysis that it is particularly important to focus on:
1. Patients at risk of PEUGIC for biological or other reasons (e.g. poor tolerance of procedure)
2. Adequate protocols for follow-up, either repeat procedures or surveillance, and whether adhered to or not
3. Clinician decision-making, including documentation
4. Booking processes
5. The quality of endoscopy procedures: protocols; care; equipment
6. Patient choice and co-morbidity
7. Action is taken when patients fail to attend procedures

A secure web-based portal will be developed by a developer working for Health Data Insight. This will involve: producing a specification based on the existing portal for the post-colonoscopy colorectal cancer root cause analysis project; agreeing on a data entry screen design and creating a data entry screen; testing a mockup portal and getting feedback; undertaking any portal changes; and finalising the specification and pushing the PEUGIC pages to the live portal.

The portal will then be piloted in two trusts with data entry on PEUGIC cases for those trusts. Feedback will be sought on the data entry screens and portal changes made as needed.

A second pilot phase will then be undertaken in 10 trusts with data entry on the portal for PEUGIC cases in those trusts. Further portal changes will be made following meetings with feedback on the data entry screens and any portal changes needed. Contingency will be allowed for additional changes, checking, and preparation for the portal to go live.

3. National rollout of secure web-based root cause analysis tool
The process for account registration and validation will follow that of the post-colonoscopy colorectal cancer root cause analysis project via an account verification Standard Operating Procedure. User guides will be created for the portal and other relevant user documents (duty of candour guidance, information governance information, information for other endoscopists, etc.).

We will advertise the launch of the PEUGIC root cause analysis portal through partner organisations (BSG, AUGIS, JAG) and PPI partners via social media and their websites. We will also ask Cancer Alliances, the National Oesophago-gastric Cancer Audit network, endoscopy

training academies, the National Nurse Endoscopist Group, gastroenterology trainee networks and regional gastroenterology associations (e.g. Midland Gastroenterological Society) to promote the launch of and involvement in the project.

Lead endoscopists at each trust who will undertake data collection for PEUGIC cases via the portal will be identified from trusts. We will have regular follow-up meetings with lead endoscopists to ensure there are no data entry issues. We will run weekly data completeness reports to monitor data completeness. We will update data on the portal each quarter and remind trusts there will be a data refresh and further PEUGIC cases to root cause analysis.

4. Quantifying the reasons why PEUGIC occur
The portal will enable each endoscopy provider not only to be informed of each PEUGIC and the need for a root cause analysis but also facilitate this by providing a structured method to report the results of the root cause analysis that can be captured centrally and enable an analysis of the reasons for PEUGIC at a national level.

Once the results of root cause analysis data have been collated at the pilot and rollout stages of the root cause analysis tool, data release will be organised with the Office for Data Release to enable analysis by Nigel Trudgill, Nick Burr, Eva Morris and Roland Valori supported by a research fellow to assess common factors and generate population-level information as to why PEUGIC occur.

This will be by far the largest cohort of PEUGIC studied in such detail and enable us to identify e. g. high- and low-risk groups or endoscopy practices. The intelligence generated will then be used to inform effective interventions to tackle the incidence of PEUGIC through local and national quality improvement efforts.

5. Interventions to reduce the occurrence of PEUGIC and impact
For an individual endoscopy provider, a PEUGIC will be an infrequent event (we estimate 10 to 20 per year depending on the size of their service) and even less frequent for individual endoscopists (10-15 in a lifetime practice depending on their volume of endoscopy activity). It would therefore take time for a service to identify all the potentially avoidable factors. Furthermore, experience with post-colonoscopy colorectal cancer suggests that up to 20% of missed cancers are diagnosed in a different provider from the index endoscopy. Consequently, the endoscopy provider would be unaware of these PEUGIC without this project.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Root cause analysis of causes of post-endoscopy upper GI cancer (PEUGIC) assessed using a secure online proforma completed by the local endoscopy team over the course of 2 years with a national analysis of aggregated data

Secondary outcome measures
Contributory factors to PEUGIC assessed using a secure online proforma completed by the local endoscopy team over the course of 2 years with a national analysis of aggregated data

Overall study start date
01/09/2022

Completion date
04/04/2026

Eligibility

Key inclusion criteria
1. Endoscopy that did not diagnose cancer 6 to 36 months before the diagnosis date
2. Oesophageal squamous cell carcinoma or adenocarcinoma or gastric adenocarcinoma
3. Resident in England

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 2400; UK Sample Size: 2400

Key exclusion criteria
1. Oesophageal or gastric carcinomas with no endoscopy that did not diagnose cancer 6 to 36 months before the diagnosis date
2. Other types of malignancy diagnosed in the oesophagus or stomach (e.g. metastatic or neuroendocrine tumours)
3. Not resident in England

Date of first enrolment
17/07/2023

Date of final enrolment
29/10/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sandwell General Hospital [Lead]
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
http://www.swbh.nhs.uk/

ROR
https://ror.org/05mzf3276

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
National organisations responsible for endoscopy standards will encourage participation through the external approval of endoscopy units and share the learning from missed cancer cases with hospitals throughout the UK.

A summary of the detailed analysis of missed cancer cases will be presented at conferences and published in medical journals to further share learning internationally.

Intention to publish date
04/10/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. No patient-identifiable data will be analysed or published.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.4	28/07/2023	16/08/2023	No	No