ISRCTN44918181 https://doi.org/10.1186/ISRCTN44918181

Identifying the factors that can improve the quality of flexible telescopic examination (endoscopy) of gullet, stomach and small bowel by analysing the information of the patients who were diagnosed with upper gastrointestinal cancer and had endoscopy prior to diagnosis and by analysing the national endoscopic database

Submission date 28/01/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 27/12/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 28/12/2023	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

In the UK, 16,800 people are diagnosed with upper gastrointestinal (GI) cancers each year, which mainly include cancers in the oesophagus and stomach (and the smaller proportion of the first part of the small intestine, also called the duodenum). Unfortunately, the outlook in people with these cancers is not good. One potentially important factor contributing to these poor outcomes is how these cancers are diagnosed. Endoscopy (a flexible telescopic examination of the oesophagus and stomach) is the standard way to identify cancers in the oesophagus and stomach. In the UK, 1.2 million endoscopies are performed each year. However, the current variation in the quality of endoscopies is not known. Previous research has shown that both around the world and specifically in the UK, many people have an endoscopy that does not diagnose upper GI cancer but then they are subsequently found to have upper GI cancer between 6 months and 3 years later. This occurs in about 10% of all people diagnosed with upper GI cancers and is called post endoscopy upper GI cancers (POUGIC). The aim of this study is to improve the quality of endoscopy for all patients in the UK by identifying potential quality indicators for endoscopy and reduce the risk of POUGIC.

Who can participate?

The researchers will request unidentifiable information for patients who were diagnosed with upper gastrointestinal cancers in the UK from 01/01/2009 to 31/12/2018

What does the study involve?
The data will be linked with records of endoscopies to identify the patients who underwent endoscopy within 3 years prior to their cancer diagnosis. This will allow the researchers to identify the patients who had endoscopy within 6 months to 36 months prior to their cancer diagnosis which did not diagnose the cancer (POUGIC) and data for this group of patients will be used as cases. The controls will be the group of patients who had endoscopy within 6 months of their cancer diagnosis. The researchers will work out the variation in POUGIC rates between NHS providers. This will later help them to compare the hospitals with the lowest (best) POUGIC rates with the hospitals with the highest (worst) rates.
The researchers will also examine factors associated with the diagnosis of upper GI cancer and examine established quality indicators. They will compare the differences in these indicators between the 25% of hospitals with the lowest and highest rates of POUGIC to see which factors differentiate between the two groups of hospitals.
These indicators will be then reviewed by a panel of medical experts and laypeople, who will discuss the practicability of these evidence-based measures. They will then be used in future in a randomised controlled trial to intervene to improve endoscopy quality and reduce POUGIC rates.

What are the possible benefits and risks to the participants?
There is no direct involvement of the patients so there are no potential risks to any patient. Data will be de-identified before transfer to research team and it will be stored in a secured toolkit meeting NHS data protection standards. The researchers believe that the study will help to improve the quality of endoscopy in the UK and potentially reduce the risk of missing cancers on endoscopy which will improve outcomes in cancer patients.

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

When is the study starting and how long is it expected to run for?
July 2020 to October 2022

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Nigel Trudgill
nigel.trudgill@nhs.net

Contact information

Type(s)
Public

Contact name
Dr Nigel Trudgill

Contact details
Gastroenterology Department
Sandwell and West Birmingham NHS Trust
Birmingham
United Kingdom
B71 4HJ

+44 (0)1215072577
nigel.trudgill@nhs.net

Type(s)
Scientific

Contact name
Dr Nigel Trudgill

Contact details
Gastroenterology Department
Sandwell and West Birmingham NHS Trust
Birmingham
United Kingdom
B71 4HJ
+44 (0)1215072577
nigel.trudgill@nhs.net

Type(s)
Scientific

Contact name
Dr Umair Kamran

Contact details
Gastroenterology Department
Sandwell and West Birmingham NHS Trust
Birmingham
United Kingdom
B71 4HJ
+44 (0)7460491718
umair.kamran1@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
289695

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR201571, CPMS 48065, IRAS 289695

Study information

Scientific Title

Identifying procedure-adjusted quality indicators for upper gastrointestinal endoscopy from multivariable analysis of cohorts with post-endoscopy upper gastrointestinal cancer (POUGIC) in the National Endoscopy Database (NED)

Study objectives
To identify indicators of high-quality endoscopy of the oesophagus, stomach and duodenum through analysis of patients with oesophagus, stomach and duodenal cancer who have an endoscopy that does not diagnose the cancer and analysis of a large database of all endoscopies in the UK to identify endoscopy quality indicators that vary between hospitals with low and high rates of not diagnosing cancer at endoscopy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/01/2021, London - South East Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8085, +44 (0)207 104 8104, +44 (0)207 104 8265; londonsoutheast.rec@hra.nhs.uk), REC ref: 20/PR/1003

Study design
Observational case-control study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Upper gastrointestinal cancer

Interventions
The researchers will request unidentifiable information for the patients who were diagnosed with upper gastrointestinal cancers in the UK from 01/01/2009 to 31/12/2018 from National Cancer Registration and Analysis Service (NCRAS). This data will be linked with the record of endoscopies in Hospital Episode Statistics (HES) to identify the patients who underwent endoscopy within 3 years prior to their cancer diagnosis. This will allow the researchers to identify the patients who had endoscopy within 6 months to 36 months prior to their cancer diagnosis that did not diagnose the cancer (POUGIC) and data for this group of patients will be used as cases. The controls will be the group of patients who had endoscopy within 6 months of their cancer diagnosis. The researchers will work out the variation in POUGIC rates between NHS providers. This will later help them to compare the hospitals with the lowest (best) POUGIC rates with the hospitals with the highest (worst) rates.

The researchers will also use a large dataset from the National Endoscopy Database (NED) to examine factors associated with the diagnosis of upper GI cancer and examine established quality indicators. They will compare the differences in these indicators between the 25% of hospitals with the lowest and highest rates of POUGIC to see which factors differentiate between the two groups of hospitals.

These indicators will be then reviewed by a panel of medical experts and lay people, who will discuss the practicability of these evidence-based measures. They will then be used in future in a randomized controlled trial to intervene to improve endoscopy quality and reduce POUGIC rates.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Evidence-based procedure-adjusted quality indicators for upper gastrointestinal endoscopy which can reduce the risk (odds) of post endoscopy upper gastrointestinal cancer, identified by analysing linked National Cancer Registration and Analysis Service (NCRAS) database and Hospital Episode Statistics (HES) for 01/01/2009 to 31/12/2018 and using the National Endoscopy Database (NED) for 01/10/2021 to 31/12/2021

Key secondary outcome(s))
1. Factors associated with post endoscopy upper gastrointestinal cancers (POUGIC) measured using linked National Cancer Registration and Analysis Service (NCRAS) database and Hospital Episode Statistics (HES) for 01/01/2009 to 31/12/2018
2. Rates of POUGIC cases across NHS hospitals measured using linked National Cancer Registration and Analysis Service (NCRAS) database and Hospital Episode Statistics (HES) for 01 /01/2009 to 31/12/2018

Completion date
31/10/2022

Eligibility

Key inclusion criteria
1. All patients 18 years of age and over at diagnosis, who are diagnosed with oesophageal, gastric and duodenal cancers from 01/01/2009 to 31/12/2018, identified in National Cancer Registration and Analysis Service (NCRAS)
2. All endoscopies performed and recorded in Hospital Episode Statistics (HES) in England between 01/01/2006 to 31/12/2018 in patients identified with oesophageal, gastric and duodenal cancer from NCRAS data
3. 200,000 upper gastrointestinal endoscopies performed in the UK and recorded in National Endoscopy Database (NED)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Paediatric population (<18 years)
2. Residents outside England

Date of first enrolment
02/11/2020

Date of final enrolment
30/06/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sandwell and West Birmingham NHS Trust
Hallam St
West Bromwich
Birmingham
United Kingdom
B71 4HJ

Sponsor information

Organisation
Sandwell & West Birmingham Hospitals NHS Trust

ROR
https://ror.org/05mzf3276

Funder(s)

Funder type
Government

Funder Name

National Institute for Health Research

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

Individual participant data (IPD) sharing plan
NCRAS will only provide anonymised data so the researchers won't receive any patient-level data. Data will be transferred to a data security protection compliant toolkit at the University of Birmingham where it will be analysed and following that it will be archived at Sandwell General Hospital (study sponsor).

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 0.3	14/12/2020	27/12/2023	No	No