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Predicting the risk of digestive diseases using a questionnaire approach

Submission date 02/08/2022	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 08/08/2022	**Overall study status** Ongoing	
Last Edited 18/07/2023	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims

There are numerous lifestyle-altering diseases in the UK for which patients undergo multiple invasive tests before they can be properly diagnosed. These tests are often uncomfortable and inconvenient for patients, in addition to being very costly for the National Health Service (NHS). They typically involve a degree of risk to patients (e.g. bleeding and bowel rupture during endoscopy; or harmful radiation exposure from scanning). Many of these tests also tend to have normal results, since only a small fraction of patients are eventually diagnosed with the disease being sought. This study will focus on using analysis of symptoms and risk factors to predict patients' risk of developing diseases.

Who can participate?

People who may already have had an endoscopy, or are due to have an endoscopy, to check for abnormalities in the gullet (food pipe or oesophagus). Such abnormalities may include inflammation of the gullet wall (e.g. oesophagitis), pre-cancerous conditions (e.g. Barrett's oesophagus) and even cancer of the gullet (oesophageal cancer).

What does the study involve?

You will be asked to sign a consent form to indicate that you are willing to participate in the study. A member of our research team will help you to complete a simple electronic questionnaire about your sociodemographic details (e.g. age, gender, smoking status) and your symptoms (e.g. heartburn, swallowing difficulties, unexplained weight loss, nausea and vomiting). We will also ask you for details of your previous medical history, medication use and family medical history of certain illnesses.

Your participation in the study will take about 30 minutes of your time in total (from reading the consent forms to completing the questionnaire). Your data will subsequently be analysed by our research team to identify the most important factors in predicting the risk of bowel disease as accurate as possible

On some occasions, some patients may be invited to complete further questionnaires in the future, but this, will be entirely your choice, and there will no obligation to continue with the study if you do not wish to do so.

What are the possible benefits and risks of participating?
You will not benefit directly by taking part but may help many other patients in the future by identifying those at high risk of gullet disease via a quick, cheap and simple test using a set of questions. This will help doctors prioritise high-risk patients who need urgent assessment and treatment. It will also save exposing low-risk patients to unnecessary procedures; save significant time and effort for patients, doctors and nurses; and save the NHS and other healthcare organisations significant amounts of money.

The questions you will be asked in the questionnaire are about your health background (e.g. smoking and alcohol consumption) and symptoms that your GP or specialist would already have asked you previously – these questions should therefore not be difficult or upsetting to answer. There is no additional risk involved.

This study aims to compare your questionnaire answers with any diagnosis established by your clinical care team. Therefore, you do not need to worry that the study will reveal any new health-related information about yourself.

Where is the study run from?
University College London (UCL) (United Kingdom)

When is the study starting and how long is it expected to run for?
June 2019 to January 2030

Who is funding the study?
1. Rosetrees Trust (United Kingdom)
2. Guts UK (United Kingdom)

Who is the main contact?
Professor Laurence Lovat (United Kingdom)
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
262349

Protocol serial number
IRAS 262349, Protocol number: 122257, CPMS 42781

Study information

Scientific Title
Predicting RIsk of diSease using detailed Questionnaires (RISQ)

Acronym
RISQ

Study objectives
This study aims to create a low-cost predictive tool that:
1. Accurately identifies individuals with a low risk of developing the disease of interest (we will start with oesophageal cancer) so that they can be saved from expensive, invasive, and unpleasant examinations and 2. Identifies patients at high risk of developing these diseases so that they can be treated by minimally invasive techniques and avoid getting the disease at all

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/09/2019, South Central - Oxford B Research Ethics Committee (Whitefriars, Level 3, Block B, Lewin's Mead, Bristol, BS1 2NT, United Kingdom; +44 (0)207 104 8178; nrescommittee.southcentral-oxfordb@nhs.net), ref: 19/SC/0382

Study design
Multicentre observational cross-sectional questionnaire-based study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prediction of risk of gastrointestinal diseases

Interventions
A symptom and risk factor questionnaire will be developed based on known symptoms and risk factors for the studied diseases. Patients will be selected in order to identify a series of groups

with different risk profiles to compare, and the presumed or confirmed diagnosis for each patient will be recorded. Novel artificial intelligence techniques will be used to analyse the questionnaire response data to identify highly accurate profiles to predict the presence of disease and disease risk. Once we have confirmed this accuracy, we aim to create a cheap and quick screening test, so that only high-risk patients will in the future need to undergo invasive investigations. This will save the NHS and other healthcare systems significant amounts of money worldwide while saving patients across the world time and inconvenience and reducing their risk of complications from unnecessary investigations.

We will divide our colorectal cohort into the following four groups:
1. Normal colonoscopy (including those with hyperplastic polyps only)
2. Low-risk colon lesions, as defined by the British Society of Gastroenterology guidelines on colon polyp risk
3. High-risk pre-cancerous polyps
4. Invasive cancer
We will further divide cancers by the Dukes stage to differentiate between low- and high-risk diseases. We will look at those with locally advanced cancer and metastatic cancer separately. As most of the patients referred through the urgent '2-week pathway' do not actually have cancer, the patient cohort will be enriched with patients with these more advanced lesions.

We will divide our oesophageal cohort into the following four groups:
1. Normal gastroscopy
2. Low-risk lesions (i.e. non-dysplastic Barrett's oesophagus)
3. High-risk lesions (i.e. dysplasia and intra-mucosal carcinoma)
4. Invasive oesophageal cancer.
We will consider those with locally advanced cancer and metastatic cancer separately. Most of the patients referred through the urgent '2-week wait' pathway do not actually have cancer, and so the patient cohort will be enriched with patients with these more advanced lesions.

Healthy volunteers for the control arm who do not have the disease under investigation will be identified by members of the study team. Volunteers will be invited to take part either by an email mailshot (for example to university staff and students) or when they attend hospital appointments with their relatives.

Intervention Type
Other

Primary outcome(s)
Prediction of risk of gastrointestinal cancer measured using a symptom-based risk factor questionnaire prior to endoscopy of the upper gastrointestinal tract

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

Completion date
01/01/2030

Eligibility

Key inclusion criteria

Healthy volunteers for the control arm:
1. Healthy volunteer relatives of patients attending hospital appointments
2. University staff, students and their friends

Patients in the observational arm:
1. Suspected or confirmed disease diagnosis of interest
2. Competent to provide consent for enrolment, and must sign an informed consent form

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Inability to give informed consent in English, or in the presence of an English translator
2. Aged 17 years old and under
3. Pregnancy

Date of first enrolment
01/01/2020

Date of final enrolment
01/01/2030

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Lister Hospital
Coreys Mill Lane
Stevenage
United Kingdom
SG1 4AB

Study participating centre
Whittington Health NHS Trust
The Whittington Hospital
Magdala Avenue
London
United Kingdom
N19 5NF

Study participating centre
Wigan and Leigh Health Services NHS Trust
Royal Albert Edward Infirmary
Wigan Lane
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WN1 2NN

Study participating centre
Princess Alexandra Hospital
Hamstel Road
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United Kingdom
CM20 1QX

Study participating centre
North Middlesex University Hospital NHS Trust
North Middlesex Hospital
Sterling Way
London
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N18 1QX

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Rosetrees Trust

Alternative Name(s)
Rosetrees, Teresa Rosenbaum Golden Charitable Trust

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Guts UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Interim results article	Development and validation of a multivariable risk factor questionnaire to detect oesophageal cancer in 2-week wait patients	01/03/2023	18/07/2023	Yes	No