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# Saliva to predict risk of disease using transcriptomics and epigenetics

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 15/09/2017 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 04/10/2017 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 05/11/2024 | Cancer | |

## 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 CT 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. The aim of this study is to analyse symptoms, risk factors and genetic changes detected in saliva samples to predict patients' risk of developing diseases.

Who can participate?

Patients aged over 18 who are already known to have oesophageal or colorectal disease including Crohn's disease, and patients who are awaiting tests to diagnose or exclude these diseases.

What does the study involve?

Participants complete a questionnaire to obtain information regarding their symptoms and risk factors for the disease. Saliva and blood samples are collected and, when appropriate, blood and tissue samples are taken during any investigations that they are already scheduled to undergo as part of their treatment process. No additional procedures or interventions are performed on these patients, and their clinical treatment is not affected in any way. Genetic analysis is performed on these samples to see if the characteristics of the patients' saliva in combination with symptoms and other risk factors can accurately predict their disease. The saliva test results are compared with the blood and, where possible, tissue test results.

What are the possible benefits and risks of participating?

The results may help to create a cheap, portable and quick bedside test that uses patients' saliva to predict their risk of disease, so that only high-risk patients will in future need to undergo invasive investigations. This will save the NHS and other healthcare systems worldwide significant amounts of money, while saving patients across the world time, inconvenience and reducing their risk of complications from unnecessary investigations.

Where is the study run from?
1. University College London (UK)
2. University College London Hospitals NHS Trust (UK)
3. Guy's and St Thomas' NHS Foundation Trust (UK)
4. Lister Hospital (UK)
5. Frimley Park Hospital (UK)
6. Wexham Park Hospital (UK)
7. Western Sussex Hospitals NHS Foundation Trust (UK)
8. Princess Alexandra Hospital (UK)
9. Royal Albert Edward Infirmary (UK)
10. Royal Surrey County Hospital (UK)
11. Shrewsbury and Telford Hospital NHS Trust (UK)
12. UK IIBD Bioresource

When is the study starting and how long is it expected to run for?
April 2017 to March 2023

Who is funding the study?
1. Rosetrees Trust (UK)
2. CORE Digestive Disorders Foundation (UK)
3. Helmsley Charitable Trust (USA)

Who is the main contact?
Prof. Laurence Lovat

# Contact information

### Type(s)
Scientific

### Contact name
Prof Laurence Lovat

### Contact details
Research Department of Targeted Intervention
Division of Surgery & Interventional Science
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W1W 7TS

# Additional identifiers

### EudraCT/CTIS number

### IRAS number
217388

### ClinicalTrials.gov number

### Secondary identifying numbers
IRAS 217388

# Study information

### Scientific Title
Saliva to predict risk of disease using transcriptomics and epigenetics (SPIT): an observational study

### Acronym
SPIT

### Study objectives
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 CT 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, risk factors and genetic changes detected in saliva samples to predict patients' risk of developing diseases.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
West Midlands - Coventry & Warwickshire Research Ethics Committee, 28/02/2017, ref: 17/WM /0079

### Study design
Observational basic science study

### Primary study design
Observational

### Secondary study design
Case-control study

### Study setting(s)
Hospital

### Study type(s)
Screening

### Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

### Health condition(s) or problem(s) studied
Oesophageal cancer, colorectal cancer, Crohn's disease

### Interventions
A ‘symptom and risk factor’ questionnaire will be developed based on known symptoms and risk factors for the disease being studied. Saliva will be collected from patients from the identified groups representing the disease profiles being studied and appropriate control subjects and analysed for epigenetic and transcriptomic biomarkers. Matched blood samples may also be collected from patients to demonstrate whether the salivary epigenetic and transcriptomic findings match those in the blood. Where patients are already undergoing invasive tests, matched tissue samples from normal and diseased tissue may be collected to demonstrate whether the salivary epigenetic and transcriptomic findings match those in the tissue. Bioinformatics combined with novel artificial intelligence techniques will be used to analyse the samples to identify highly accurate biomarker profiles to predict the presence of both disease and disease risk.

### Intervention Type
Other

### Primary outcome measure
Epigenetic and transcriptomic biomarkers, measured using next generation sequencing of saliva /blood/tissue samples collected at single study visit

### Secondary outcome measures
Disease symptoms and risk factors, measured using questionnaire at single study visit

### Overall study start date
06/04/2017

### Completion date
01/10/2023

## Eligibility

### Key inclusion criteria
Current participant inclusion criteria as of 25/08/2021:
For the initial study of oesophageal disease, both current and new patients identified as having oesophageal disease (e.g. Barrett’s oesophagus, oesophageal cancer) will be recruited together with those being referred along the 2-week-wait cancer-target pathway. Patients without oesophageal disease attending for a clinically indicated endoscopy may be recruited as controls.

For the initial study of colorectal disease, patients will be recruited from the National Bowel Cancer Screening Programme, as well as from other patients with colorectal disease attending for colonoscopy. Patients without colorectal disease attending for a clinically indicated colonoscopy may be recruited as controls.

For patients with Crohn's disease, both the UK IBD Bioresource and participating centres will contact patients inviting them to sign up for the study online.

Previous participant inclusion criteria:
For the initial study of oesophageal disease, both current and new patients identified as having oesophageal disease (e.g. Barrett's oesophagus, oesophageal cancer) will be recruited together with those being referred along the 2-week-wait cancer-target pathway. Patients without oesophageal disease attending for a clinically indicated endoscopy may be recruited as controls.

For the initial study of colorectal disease, patients will be recruited from the National Bowel Cancer Screening Programme, as well as from other patients with colorectal disease attending for colonoscopy. Patients without colorectal disease attending for a clinically indicated colonoscopy may be recruited as controls.

### Participant type(s)
Mixed

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
2000

### Key exclusion criteria
Current participant exclusion criteria as of 25/08/2021:
1. Patients who are unable to undergo definitive investigations such as colonoscopy or surgery as a definitive pathological diagnosis will not be achievable in such instances
2. Patients who are unable to give informed consent in English, or in the presence of an English translator
3. Pregnant women
4. Patients under the age of 18 years

Previous participant exclusion criteria:
1. Patients who are unable to undergo definitive investigations such as colonoscopy or surgery as a definitive pathological diagnosis will not be achievable in such instances
2. Patients who are unable to give informed consent in English, or in the presence of an English translator
3. Pregnant women
4. Patients under the age of 21 years

### Date of first enrolment
06/04/2017

### Date of final enrolment
01/03/2023

## Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**University College London**
United Kingdom
WC1E 6BT

**Study participating centre**
**University College London Hospitals NHS Trust**
United Kingdom
NW1 2PG

**Study participating centre**
**Guy's and St Thomas' NHS Foundation Trust**
United Kingdom
SE1 9RT

**Study participating centre**
**Lister Hospital**
United Kingdom
SW1W 8RH

**Study participating centre**
**Frimley Park Hospital**
United Kingdom
GU16 7UJ

**Study participating centre**
**Wexham Park Hospital**
United Kingdom
SL2 4HL

**Study participating centre**

**Western Sussex Hospitals NHS Foundation Trust**
United Kingdom
BN11 2DH

**Study participating centre**
**Princess Alexandra Hospital**
United Kingdom
CM20 1QX

**Study participating centre**
**Royal Albert Edward Infirmary**
United Kingdom
WN1 2NN

**Study participating centre**
**Royal Surrey County Hospital**
United Kingdom
GU2 7XX

**Study participating centre**
**Shrewsbury and Telford Hospital NHS Trust**
United Kingdom
SY3 8XQ

**Study participating centre**
**IBD Bioresource**
Box 299, Cambridge BioMedical Campus
Hills Road
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United Kingdom
CB2 0QQ

# Sponsor information

**Organisation**
University College London

### Sponsor details
Joint Research Office
1st Floor, Maple House – Suite B
149 Tottenham Court Road
London
England
United Kingdom
W1T 7DN

### Sponsor type
University/education

### ROR
https://ror.org/02jx3x895

## Funder(s)

### Funder type
Charity

### Funder Name
Rosetrees Trust

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

### Funding Body Type
Private sector organisation

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

### Location
United Kingdom

### Funder Name
CORE Digestive Disorders Foundation

### Funder Name
Leona M. and Harry B. Helmsley Charitable Trust

### Alternative Name(s)

Helmsley Charitable Trust, The Leona M. and Harry B. Helmsley Charitable Trust, Leona M. & Harry B. Helmsley Charitable Trust, The Helmsley Charitable Trust

### Funding Body Type
Private sector organisation

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

### Location
United States of America

## Results and Publications

### Publication and dissemination plan
Planned publication in high-impact peer reviewed journals.

### Intention to publish date
01/10/2023

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Laurence Lovat. Data will be available after the study ends.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Other publications | | 09/03/2020 | 25/11/2020 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Results article | | 01/01/2024 | 05/11/2024 | Yes | No |