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Detection of bowel cancer using urinary biomarkers

Submission date
29/03/2018

Recruitment status
No longer recruiting

Registration date
27/02/2019

Overall study status
Completed

Last Edited
03/04/2020

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Bowel cancer is diagnosed in 40,000 people each year in the UK. Early detection and treatment of bowel cancer is important as it improves survival. This has led to a “fast-track” system to speed up waiting times and access to hospital tests. Deciding who to test is a hard for GPs and hospital doctors because bowel symptoms are common and are not usually due to cancer. In addition, not all people with a bowel cancer develop symptoms. Therefore, at present the vast majority of patients are required to undergo testing. An internal camera examination of the large bowel (colonoscopy) is the best way to look at the large bowel. This is invasive, can be uncomfortable and needs strong laxatives to prepare the bowel. There is a risk of unplanned admission to hospital and surgery. This test is also expensive and the demand is increasing in the NHS. In the UK, 300,000 people a year are referred through the fast-track system for suspected bowel cancer. Over 90% of these have normal results, meaning they have undergone unpleasant testing that did not help them. It is now possible to look at natural chemicals, produced by normal bacteria that live in everybody’s bowel, to help diagnose bowel conditions. Bowel cancer alters the chemical “signature”. The aim of this study is to test the urine of 600 people referred by their GP to the fast-track pathway for these chemicals to see how good they are at predicting bowel cancer.

Who can participate?
Patients aged 18 and over, referred by their GP for fast-track assessment due to symptoms of colorectal cancer

What does the study involve?
Participants provide a urine sample when they attend the hospital for colonoscopy or CT scanning. Participants are also asked to complete a short questionnaire collecting demographic information and some data about lifestyle including smoking status, alcohol use and dietary habit (meat eating, vegetarian or vegan diet). From that point on their clinical pathway is unaffected by participation in the study and the results of the volatile compound testing are not be available to the clinical team. At the end of their investigations (maximum of 63 days), a member of the research team accesses patient notes to collect disease outcome data coded as cancer, polyp or normal. The participants receive treatment as normal judged on the clinical data available to the clinicians caring for them. The urine samples are sent for analysis at the

University of the West of England. They are analysed using three separate machines to identify which of these machines is the best for use in a clinical setting, to take forward into a larger study. Data from the testing are then analysed along with the data about disease status in order to assess the sensitivity and reliability of the testing for the identification of patients at high risk of having colon cancer.

What are the possible benefits and risks of participating?
If the test works (helps to identify which patients can be safely reassured and which do need further testing), a larger study will be performed to confirm these findings. The goal of this research is to safely reduce the number of patients having unpleasant bowel tests without missing important diagnoses. There are no benefits or risks to the patient from participating in this study because there are no invasive tests and the clinical course of the patients isn't affected.

Where is the study run from?
1. Yeovil District Hospital NHS Foundation Trust (UK)
2. North Bristol NHS Foundation Trust (UK)
3. St James' University Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2017 to March 2020

Who is funding the study?
NIHR Research for Patient Benefit Programme (UK)

Who is the main contact?
Dr Caroline Boulind
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
v1

Study information

Scientific Title
Detection of symptomatic colorectal cancer using volatile urinary biomarkers (DISCOVER)

Acronym
DISCOVER

Study objectives
1. To determine the sensitivity and specificity of urinary volatile compound analysis for the detection of colorectal cancer and polyps
2. To estimated the test-retest reliability of urinary volatile compound testing for the detection of colorectal cancer and polyps
3. To provide and estimate the cost implication of the proposed method of urinary volatile compound testing to inform the planning of an economic evaluation in a larger cost-effectiveness study
4. To determine patient and user acceptability of urinary volatile compound testing within the context of the colorectal cancer fast track referral pathway

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – Riverside research ethics committee, 30/05/2018, ref: 18/LO/1005

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions
This observational study is investigating the feasibility of a larger study looking into the use of urinary volatile compounds in the assessment of patients with symptoms of bowel cancer. Patients referred for investigation via the colorectal cancer fast track pathway will be approached for participation. If they consent to take part, they will be asked to provide a urine sample when they attend the hospital for colonoscopy or CT scanning. Participants will also be asked to complete a short questionnaire collecting demographic information and some data about lifestyle including smoking status, alcohol use and dietary habit (meat eating, vegetarian or vegan diet). From that point on their clinical pathway is unaffected by participation in the study and the results of the volatile compound testing will not be available to the clinical team. At the end of their investigations (maximum of 63 days), a member of the research team will access patient notes to collect disease outcome data coded as cancer, polyp or normal. The participants will receive treatment as normal judged on the clinical data available to the

clinicians caring for them. The urine samples will be sent for analysis at the University of the West of England. They will be analysed using three separate machines using different types of gas chromatography. Part of the feasibility process is to identify which of these machines is the best for use in a clinical setting, to take forward into a larger study. Data from the volatile compound testing will then be analysed along with the data about disease status in order to assess the sensitivity and reliability of volatile compound testing for the identification of patients at high risk of having colon cancer. If volatile compound testing is able to identify those patients who have bowel cancer, the aim is to take this work forward into a larger study incorporating its use into clinical care. Urine testing will be used to triage patients on the fast track pathway in order to reduce the need for invasive testing such as colonoscopy, which can be painful and unpleasant for patients.

Intervention Type
Other

Primary outcome(s)
The primary outcome will consist of feasibility outcomes including recruitment rate, attrition rate (this is unlikely to relate to the patients since there isn't any follow up involving patients, but rather to loss of urine samples of problems with processing), logistics of storage and transport of urine samples, piloting of clinical data collection (extraction of disease status data from clinical records).

Another important outcome from this study is the assessment of the specificity and sensitivity of the gas chromatography techniques used in the study. These will be compared using both quantitative output data as well as logistical and technical considerations relating to their use in clinical practice. This assessment will inform the choice of which chromatography technique to take forward into a larger study.

Key secondary outcome(s))
Detection of urinary volatile biomarkers able to identify patients with colorectal cancer

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Adult patients aged 18 years and over
2. Referred by their GP for fast-track assessment due to symptoms of colorectal cancer

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Key exclusion criteria
1. Patients unable to provide written informed consent
2. Current proven urinary tract infection
3. Urine sample dipstick testing positive for nitrites
4. Antibiotic use for any reason within the past fourteen days
5. Any contraindication to colonoscopy or CT colonography
6. Any other proven or suspected cancer (except non melanoma skin cancer)
7. Patients undergoing renal replacement therapy
8. Patients with ileal conduit due to cystectomy
9. Patients with urinary catheter, urethral or suprapubic
10. Inability to provide a midstream urine sample

Date of first enrolment
01/07/2018

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Yeovil District Hospital NHS Foundation Trust
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Study participating centre
North Bristol NHS Foundation Trust
United Kingdom
BS10 5NB

Study participating centre
St James' University Hospital
Leeds

United Kingdom
LS9 7TF

Sponsor information

Organisation
Yeovil District Hospital NHS Foundation Trust

ROR
https://ror.org/00v5nyn36

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes