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Detection of bowel disease using cells from the colon

Submission date 11/06/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/06/2010	**Overall study status** Completed	
Last Edited 07/09/2016	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
The purpose of this study is to examine the differences between cells which are naturally shed from the bowel in patients with and without bowel disease. Origin Sciences Ltd has developed a device to collect these cells. It is hoped that by measuring the total amount of genetic material (DNA) in the cells, we can determine whether there is any disease of the bowel which may explain your change in bowel habit and stomach pains, and hence avoid any further invasive tests such as endoscopy (camera tests).

Who can participate?
You have been chosen because you require investigation of your bowel symptoms and may have bowel disease.

What does the study involve?
If you take part in this study, there will be no change to the investigation or any treatment you undergo for your bowel problem. As part of your normal investigation the doctor will examine your back passage (rectal examination). In this study we would in addition use a small balloon to collect cells from the rectum (lower bowel) during the examination of your back passage. This will only involve a few additional seconds compared to your normal management and will be done at the same time as the examination of the back passage. The total time for the whole examination is about 30 seconds. The amount of discomfort is minimal and less than that of a rectal examination as the balloon is soft and only 1 cm in diameter. The balloon is only inflated for ten seconds. The cells from the surface of the balloon will then be immersed in a fixative (preservation) solution. This preservation fluid ensures little or no loss of cells. The fluid is then taken to the laboratory in Cambridge (Origin Sciences Ltd) where it is processed and analysed. The samples will be looked at to see the total amount of genetic content (DNA). In previous studies we have found that an increase in the amount of DNA that is shed is associated with bowel disease. The samples will also be stored for further analysis to look at new markers in the future which may help in the early diagnosis of bowel inflammation. These markers will have no immediate effect to you or your family and would have to be tested in clinical trials before they can be shown to be reliable.

What are the possible benefits and risks of participating?
If the technique if successful, it may provide a simple method of screening for bowel disease in the future. There will be no direct benefit to you but will help patients in the future. We hope that our research will lead to the development of new treatment strategies that will improve the future medical treatment of bowel diseases. You are asked to donate your tissue freely for research that may help the patients of the future and you will not receive a financial reward either now or in the future. Your samples will not be sold for profit to other researchers. However, your samples may be used for research that may lead to the development of new drugs or treatments. In this way new drugs may eventually be marketed and companies may sell these drugs for profits. There will be no disadvantage if you do not participate in the study and it will not affect your routine care or operation. The procedure is simple and causes minimal discomfort. There are no other major risks from this procedure.

Where is the study run from?
The study is being organised by the Department of Colorectal Surgery at Leicester General Hospital, which are part of the University Hospitals of Leicester (UK).

When is the study starting and how long is it expected to run for?
June to September 2010

Who is funding the study?
The project is funded by the company, Origin Sciences Ltd, which helped develop the instrument used to collect the tissue sample.

Who is the main contact?
Mr Baljit Singh

Contact information

Type(s)
Scientific

Contact name
Mr Baljit Singh

Contact details
Leicester General Hospital
Gwendolen Road
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LE5 4PW

Additional identifiers

Protocol serial number
Version 3

Study information

Scientific Title

Quantitative analysis of DNA extracted from the rectal mucosa of patients with colorectal disease

Study objectives
The first stage of the study will investigate the hypothesis that cell exfoliation from colorectal tumours is increased compared to normal mucosa resulting in quantitative differences between cancer patients and healthy individuals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford REC C Research Ethics sub-committee, 07/06/2010, ref: 09/H0606/57

Primary study design
Observational

Study design
Prospective quantitative cohort analysis

Study type(s)
Diagnostic

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

Interventions
Consecutive outpatient patients presenting with colorectal symptoms will be offered appropriate investigation of the bowel e.g. colonoscopy, barium enema, virtual colonoscopy. The precise investigation method will follow standard NHS practice.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Assessment of correlations between DNA concentrations extracted from the rectal mucosa (DNA score) and final diagnosis in a cohort of consecutive symptomatic patients.

Key secondary outcome(s)
1. Information on DNA score ranges for individuals without colorectal conditions (no abnormality detected [NAD]) and on groups of patients with pathological conditions of different severity (IBD, polyps, diverticular disease, inflammation)
2. Determination of the optimal DNA score value as the cut-off point for selecting patients for further investigation

Completion date
17/09/2010

Eligibility

Key inclusion criteria
1. Male and female patients aged 18 or over
2. Patients who have given written informed consent
3. If a woman of child-bearing potential, must have given a negative pregnancy test

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients less than 18 years old
2. Patients taking part in another clinical study
3. Patients unable to give clear written informed consent to the study
4. Patients with confirmed inflammatory bowel disease (IBD)
5. Patients with confirmed or suspected anal cancer
6. Patients with who have had any previous gastro-intestinal malignancy
7. Patients who have undergone previous colonic resection
8. Patients who have undergone chemotherapy or radiotherapy anytime within the last 6 months
9. Patients who have received any form of bowel preparation or contrast medium within the 14 days preceding the test
10. Patients who have received any form of anaesthesia in the 48 hours preceding the test
11. Patients with clear evidence of rectal cancer at proctoscope examination
12. Patients with an anal fissure, anal fistula, advanced haemorrhoids or any other condition that may make proctoscope introduction painful and/or dangerous in the eyes of the investigator
13. Patients with a faecally loaded rectum at proctoscope examination
14. Women who are pregnant or suspect that they may be pregnant
15. Patients with known Hepatitis B or HIV infection
16. Patients suffering from chronic alcohol abuse (over 30 units consumed per week on average)
17. Patients with a history of allergic reactions to compounds of similar chemical or biological composition to the device
18. Patients unable to comply with the protocol requirements (compliance)

Date of first enrolment
17/06/2010

Date of final enrolment
17/09/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
Origin Sciences (UK)

ROR
https://ror.org/01g15q926

Funder(s)

Funder type
Industry

Funder Name
Origin Sciences (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request