

Colon cancer detection by measuring DNA of cells collected from rectum: A pilot study

Submission date 20/05/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 29/05/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 01/08/2012	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PTG95-96

Study information

Scientific Title
Colorectal cancer screening by quantitative analysis of DNA isolated from exfoliated cells sampled from the surface of human rectal mucosa: A pilot study

Acronym

PTG (Pilot Trial Guildford)

Study objectives

Cell exfoliation from the surface of colorectal tumours is much more intensive than from normal colorectal mucosa. The hypothesis is that exfoliated cells are transferred to the rectum within mucocellular layer separating colon mucosa from the gut contents, and accumulation of exfoliated cells in cancer patients is much greater comparing to healthy individuals. It is suggested that this phenomenon can be used for colorectal cancer early detection and screening.

Please note that another study closely related to this study has been registered with ISRCTN95403112 (<http://www.controlled-trials.com/ISRCTN95403112>)

Ethics approval required

Old ethics approval format

Ethics approval(s)

South West Surrey Local Research Ethics Committee. Date of approval: 03/04/2004 (ref: 04/Q1909/38)

Primary study design

Observational

Study design

Observational pilot study

Study type(s)

Screening

Health condition(s) or problem(s) studied

Colorectal cancer; inflammatory bowel disease

Interventions

This study was conducted with two distinct groups of participants:

1. Patients presenting colorectal symptoms (outpatient group)
2. Patients with clinical diagnosis of colorectal malignancies

This pilot study did not follow a "case-control" pattern; the two groups were enrolled for different purposes. The outpatient group provided samples for prospective analysis of DNA scores in individuals with a range of colorectal conditions. Investigation of the known cancer group addressed possible differences between tumours of the proximal and distal colon.

Interventions:

Samples of exfoliated cells were collected from the surface of rectal mucosa using proctoscopy and a short (10 sec) inflation in the rectal cavity of a cell-collecting balloon. The procedure was minimally invasive and was completed within five minutes. The collected samples were assessed for DNA contents.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

DNA yields from exfoliated materials (DNA scores) are assessed in terms of their predictive value in detecting the presence of serious colorectal conditions (colorectal cancer and inflammatory bowel disease)

Key secondary outcome(s)

No secondary outcome measures

Completion date

30/09/2006

Eligibility**Key inclusion criteria**

Two different groups of participants were recruited:

1. Consecutive outpatients presenting colorectal symptoms and selected for diagnostic full colonoscopy
2. Consecutive patients with clinical diagnosis of colorectal malignancies prepared for operations in the Royal Surrey County Hospital (Guildford)

Note: In this small pilot study there was no sex and age limitations. All patients were over 35 of age.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Extensive surgical interventions in the colorectal region in the past

Date of first enrolment

01/04/2005

Date of final enrolment

30/09/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Colonix Medical Limited

Cambridge

United Kingdom

CB22 3AT

Sponsor information**Organisation**

Colonix Medical Ltd (UK)

ROR

<https://ror.org/01g15q926>

Funder(s)**Funder type**

Industry

Funder Name

Colonix Medical Ltd (UK)

Funder Name

East of England Development Agency, Grant for Research and Development 2006 (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2009		Yes	No