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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Observational pilot study

Primary study design
Observational

Secondary study design
Cross-section survey

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet

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 measure
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)

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/04/2005

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

Age group

Adult

Sex
Both

Target number of participants
100-130 outpatients with unknown status and 50-60 patients with clinical diagnosis of colorectal cancer

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
England

United Kingdom

Study participating centre
Colonix Medical Limited
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Sponsor information

Organisation
Colonix Medical Ltd (UK)

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Sponsor type
Industry

Website
http://www.colonixmedical.com

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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