

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

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|--|---|---|
| Submission date 20/05/2008 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 29/05/2008 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 01/08/2012 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Alexandre Loktionov

Contact details
Colonix Medical Limited
Babraham Research Campus
Babraham
Cambridge
United Kingdom
CB22 3AT
+44(0)1223 496095

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

Cambridge

United Kingdom

CB22 3AT

Sponsor information

Organisation

Colonix Medical Ltd (UK)

Sponsor details

Babraham Research Campus

Babraham

Cambridge

United Kingdom

CB22 3AT

+44(0)1223 496092

alex.loktionov@colonixltd.co.uk

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 |