

Colon cancer detection by measuring DNA of cells collected from rectum: A case-control study

Submission date 08/07/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 16/07/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 31/07/2012	Condition category Cancer	☐ 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 Ltd
Babraham Research Campus
Babraham
Cambridge
United Kingdom
CB22 3AT

Additional identifiers

Protocol serial number

VTD/PTO 06

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 case-control study

Acronym
VTD/PTO

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 trial closely related to this study has been registered with ISRCTN30255103 (<http://www.controlled-trials.com/ISRCTN30255103>)

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Oxford Research Ethics Committee. Date of approval: 15/02/2006 (ref: 06/Q1605/21)
2. South West Surrey Local Research Ethics Committee. Date of approval: 12/04/2006 (Amendment 4 to ref: 04/Q1909/38)

Primary study design

Observational

Study design

Observational case-control study

Study type(s)

Screening

Health condition(s) or problem(s) studied

Colorectal cancer

Interventions

This study was conducted with two distinct groups of participants:

1. Patients with clinical diagnosis of colorectal malignancies
2. Clinically healthy volunteers

In this case-control study both cancer patients and healthy volunteers provided samples for the analysis of DNA scores.

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 colorectal cancer

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/11/2007

Eligibility

Key inclusion criteria

1. Case group: Consecutive patients (both males and females) with clinical diagnosis of colorectal malignancies recruited by Colorectal Surgery Department of the John Radcliffe Hospital (Oxford, UK)
2. Control group: Clinically healthy volunteers (both males and females), age 50-70, recruited by Honiton Hospital (Honiton, UK)

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. For both case and control groups: Extensive surgical interventions in the colorectal region or colorectal malignancies in the past
2. For control group: Chronic colorectal conditions (even asymptomatic)

Date of first enrolment

01/05/2006

Date of final enrolment

01/11/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Colonix Medical Ltd
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)

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	15/04/2010		Yes	No