

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

<b>Submission date</b> 08/07/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/07/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/07/2012	<b>Condition category</b> 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

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### Contact details

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## 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)

**Study design**

Observational case-control study

**Primary study design**

Observational

**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?
<a href="#">Results article</a>	results	15/04/2010		Yes	No