

# 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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Case-control study

## Study setting(s)

Not specified

## Study type(s)

Screening

## Participant information sheet

## 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 measure**

DNA yields from exfoliated materials (DNA scores) are assessed in terms of their predictive value in detecting the presence of colorectal cancer

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/05/2006

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

100-110 healthy controls and 50-60 patients with clinical diagnosis of colorectal cancer

**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**

England

United Kingdom

**Study participating centre**

Colonix Medical Ltd

Cambridge

United Kingdom

CB22 3AT

**Sponsor information****Organisation**

Colonix Medical Ltd (UK)

**Sponsor details**

Babraham Research Campus

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enquiries@colonixmedical.com

**Sponsor type**

Industry

**Website**

<http://www.colonixmedical.com>

ROR

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

## Funder(s)

**Funder type**

Industry

**Funder Name**

Colonix Medical Ltd (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?
<a href="#">Results article</a>	results	15/04/2010		Yes	No