ISRCTN95403112 https://doi.org/10.1186/ISRCTN95403112

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

Submission date	Recruitment status	[_] Prospectively registered
08/07/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/07/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/07/2012	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
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)

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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)

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	15/04/2010		Yes	No