# Implementation of colorectal cancer screening with Faecal Occult Blood Test (FOBT) in the Netherlands

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
23/08/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/08/2007	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
21/12/2011	Cancer			

## Plain English summary of protocol

Not provided at time of registration

## Study website

http://www.colonca.nl

## Contact information

## Type(s)

Scientific

#### Contact name

Dr L.G.M van Rossum

#### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

CRC01

## Study information

## Scientific Title

## Acronym

**FOCUS** 

## **Study objectives**

Implementation of colorectal cancer screening with Faecal Occult Blood Test (FOBT) in the Netherlands is feasible.

Please note that the follow-up study to this randomised controlled trial can be found at ISRCTN94861265: Screening Or NO Screening: differences in survival during follow-up after random colorectal cancer screening with faecal occult blood test or no screening.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the Dutch Health Council on the 3rd November 2005 (ref: 2005 /03WBO).

## Study design

Multicentre, randomised, active controlled, parallel group trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

GP practice

## Study type(s)

Quality of life

## Participant information sheet

## Health condition(s) or problem(s) studied

Colorectal cancer screening with Faecal Occult Blood Test (FOBT)

#### **Interventions**

- 1. Invitation by information of municipal database versus general practitioner database
- 2. Faecal Occult Blood Test (FOBT): Guaiac-FOBT versus Immunochemical FOBT one day or two day testing
- 3. If FOBT positive: colonoscopy

## Timepoints:

T0 = randomisation

T1 = invitation of the individuals randomised to the screening group

T2 = receive date of the test

T3 = evaluation date of the test in the laboratory

T4 = positive (including invitation for pre-colonoscopy consultation) or negative result letter

T5 = pre-colonoscopy consultation

T6 = colonoscopy

T7 = further treatment if necessary

T8 = start follow-up (for no screening group T8 starts immediately, for the screening group with negative test T8 is consecutive after T3)

T9 = follow-up 1 year

T10 = follow-up 2 years

T11 = follow-up 3 years

## Intervention Type

Other

#### **Phase**

**Not Specified** 

## Primary outcome measure

Response rate per FOBT, measured at T2.

## Secondary outcome measures

- 1. Positivity rate, measured at T4
- 2. Detection rate, measured at T6
- 3. Positive predictive value, measured at T6
- 4. Specificity, measured at T6

## Overall study start date

01/05/2006

## Completion date

01/05/2016

## Eligibility

## Key inclusion criteria

Men and women 50 to 75 years of age.

## Participant type(s)

Patient

## Age group

#### Senior

#### Sex

**Not Specified** 

## Target number of participants

20000

## Key exclusion criteria

Living in an institution or similar.

## Date of first enrolment

01/05/2006

## Date of final enrolment

01/05/2016

## Locations

## Countries of recruitment

Netherlands

# Study participating centre Radboud University Nijmegen Medical Centre

Nijmegen Netherlands 6500 HB

## Sponsor information

## Organisation

University Medical Centre St. Radboud (The Netherlands)

## Sponsor details

Department of Gastroenterology and Hepatology Nijmegen Netherlands 6500 HB

## Sponsor type

Hospital/treatment centre

#### Website

http://www.umcn.nl/homepage

## ROR

https://ror.org/05wg1m734

## Funder(s)

## Funder type

Research organisation

## Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

## **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	15/08/2009		Yes	No
Results article	patient perspective results	01/11/2010		Yes	No
Results article	cost effectiveness results	15/04/2011		Yes	No
Results article	results	01/07/2011		Yes	No