# 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

## Contact information

## Type(s)

Scientific

#### Contact name

Dr L.G.M van Rossum

#### Contact details

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## Additional identifiers

Protocol serial number 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

## Study type(s)

Quality of life

## 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(s)

Response rate per FOBT, measured at T2.

## Key secondary outcome(s))

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

## Completion date

01/05/2016

# **Eligibility**

## Key inclusion criteria

Men and women 50 to 75 years of age.

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Senior

#### Sex

**Not Specified** 

## 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

# Sponsor information

## Organisation

6500 HB

University Medical Centre St. Radboud (The Netherlands)

#### **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**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	<b>Details</b> results	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		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
Study website	Study website	11/11/2025	11/11/2025	No	Yes