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

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.colonca.nl

Contact information

Type(s)
Scientific

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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