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Screening Or NO Screening: differences in survival during follow-up after random colorectal cancer screening with faecal occult blood test or no screening

Submission date 23/08/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/08/2007	**Overall study status** Completed	
Last Edited 01/07/2016	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CRC02; NTR1010

Study information

Scientific Title
Screening Or NO Screening: differences in survival during follow-up after random colorectal cancer screening with faecal occult blood test or no screening

Acronym
SONOS

Study objectives
Survival after screening for colorectal cancer with faecal occult blood test is increased compared with no screening.

Please note that this is the follow-up trial to ISRCTN57917442: Implementation of colorectal cancer screening with Faecal Occult Blood Test (FOBT) in the Netherlands.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval provisionally received from the Dutch Health Council, 03/11/2005, ref: 2005 /03WBO

Primary study design
Interventional

Study design
Randomised active-controlled parallel-group trial

Study type(s)
Screening

Health condition(s) or problem(s) studied
Colorectal cancer screening with Faecal Occult Blood Test (FOBT)

Interventions
Faecal occult blood test versus no test.

Timepoints (included in original trial - see hypothesis):
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)
Survival

In each year of the follow-up (timepoints T9 - T11), the population will be censored for:
1. Mortality of colorectal cancer
2. Mortality of other causes
3. Other reasons for loss to follow-up

Key secondary outcome(s)
No secondary outcome measures

Completion date
01/09/2017

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
All

Key exclusion criteria
Living in an institution or similar

Date of first enrolment
01/09/2007

Date of final enrolment
01/09/2017

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 (Netherlands)

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Radboud Universitair Medisch Centrum

Alternative Name(s)
Radboudumc, Radboud University Medical Center, Radboud University Nijmegen Medical Center, RUNMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration