

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	☒ Prospectively registered ☐ Protocol
Registration date 23/08/2007	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 01/07/2016	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

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
Radboud University Nijmegen Medical Centre
Department of Gastroenterology and Hepatology
Nijmegen
Netherlands
6500 HB
+31 (0)24 361 7272
L.vanRossum@mdl.umcn.nl

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

Study design

Randomised active-controlled parallel-group trial

Primary study design

Interventional

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