

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

<b>Submission date</b> 23/08/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/08/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/07/2016	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Screening

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

## 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 measure**

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

### **Secondary outcome measures**

No secondary outcome measures

### **Overall study start date**

01/09/2007

### **Completion date**

01/09/2017

## **Eligibility**

### **Key inclusion criteria**

Men and women 50 to 75 years of age

### **Participant type(s)**

Patient

### **Age group**

Senior

### **Sex**

Both

**Target number of participants**

20000

**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)

**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

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

## 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