# Implementation of population screening for colorectal cancer by repeated fecal occult blood test in the Netherlands

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON23143

**Source**
Nationaal Trial Register

**Brief title**
CRC-SCR

**Health condition**

colorectal cancer, average risk individuals

### Sponsors and support

**Primary sponsor:** Dep. of Gastroenterology, Academic Medical Center Amsterdam
**Source(s) of monetary or material Support:** Zon-MW, The Netherlands Organization for Health Research and Development

### Intervention

### Outcome measures

**Primary outcome**

- Attendance rate

**Secondary outcome**

- Burden of FOBT

# Study description

**Background summary**

Colorectal cancer (CRC) is one of the major causes of death in the Netherlands, accounting for over 4500 deaths in 2005. CRC morbidity and mortality can be reduced by population screening. Of the

currently available screening tests, the effectiveness of screening with fecal occult blood test (FOBT) is

the only one with documented efficacy in randomized controlled clinical trials.

FOBT is a test with a relatively low sensitivity. On the other hand, it is not invasive and very cheap.

Biannual performance of FOBT could result in a cumulative yield that is competitive with the yield of

screening with more sensitive tests performed less frequently. Most international guidelines on

FOBT-based screening now recommend biannual screening.

The benefits of a screening program depend not only on the efficacy, but also on the participation rate.

Biannual screening is only feasible if the participation rate in such a screening program does not

substantially decline during subsequent screening rounds.

So far, it is unclear to what extent screening participants respond positively to invitations for repeated

screening in the Dutch situation and how many of them actually will participate in further

screening

rounds. Preliminary analysis of questionnaires from the first screening round of the Dutch FOBT

implementation trial suggests that a significant percentage of the participants would not participate again

in an FOBT-based screening program.

In this proposal we intend to study the implementation of repeated FOBT in participants of

invitation-based FOBT population screening in the Netherlands. The study will build on the first

implementation study of FOBT screening in the Amsterdam region which has almost been completed.

Eligible for the current study proposal will be the same 10.000 persons aged 50 to 74 years that were

selected for the first screening round in the above mentioned implementation study. This group will

consist of non participants of the first round as well as those that tested negative on the FOBT test.

Those people that were FOBT-positive but declined undergoing a colonoscopy will also be included in

the second round. Only FOBT-positives that underwent a colonoscopy will be excluded since they have

undergone the current gold standard of colon imaging. The above mentioned group (± 9.750 persons)

will receive another invitation to participate in FOBT screening two years after the first invitation. In this

study we intend to use the immunochemical FOBT (OC-Sensor). In case of a positive FOBT they will be

referred for colonoscopy. The main outcome measure of this study is the second round participation

rate.

Validated questionnaires, provided before and after test results, will measure patients' experience with

the screening program. Most important aspects are the perception of the repeated FOBT, the

understanding of the test results, the possibility to make a well-informed choice, and the preference of

screening method. Furthermore, we will incorporate the results of this two-yearly FOBT-based

population screening program in a model-based cost-effectiveness analysis of CRC-screening in the

Netherlands.

The organization of the study will be done by the Departments of Gastroenterology and Hepatology and

Clinical Epidemiology, Biostatistics and Bioinformatics in the AMC, together with the regional

Comprehensive Cancer Center (IKA). The cost-effectiveness analysis will be performed in collaboration

with the department of Public Health of the Erasmus MC.

The results of this implementation study will enable an evidence-based comparison of the different

FOBT-strategies for CRC-screening in the Netherlands from a point of feasibility and cost-effectiveness.

**Study design**

- Baseline (after completion of the test, before notification of the testresult)

**Intervention**

FOBT with collection paper vs FOBT without collection paper

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Age 50-74

2. Living in Almere, Amsterdam

3. Watergraafsmeer, Diemen

## Exclusion criteria

1. FOBT positive in first round

# Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-06-2008 |
| Enrollment: | 10000 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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|---|---|
| Date: | 26-05-2008 |
| Application type: | First submission |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID |
|---|---|
| NTR-new | NL1281 |

| Register | ID |
| --- | --- |
| NTR-old | NTR1327 |
| Other | : 120710007 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Study results

**Summary results**
N/A