

# Yield and burden of surveillance CT colonography in a population screening trial for colorectal cancer.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON23280

### Source

Nationaal Trial Register

### Brief title

COCOS Surveillance

### Health condition

Colorectal cancer, Adenomatous polyp

## Sponsors and support

**Primary sponsor:** Academic Medical Center (AMC) and Erasmus Medical Center (EMC) Rotterdam

**Source(s) of monetary or material Support:** None

## Intervention

## Outcome measures

### Primary outcome

The final CT colonography screening yield for advanced neoplasia per 100 invitees through determining surveillance CT colonography yield.

## Secondary outcome

1. Surveillance CT colonography participation;
2. Burden of awaiting surveillance CT colonography;
3. Pain and burden of surveillance CT colonography and compare this with the initial screening CT colonography;
4. Diagnostic performance of radiologists and technicians and to compare the performance.

## Study description

### Background summary

Colorectal cancer has a prevalence of approximately 5% and mortality reduction is possible by detection precursor lesions (most importantly advanced adenomas) followed by removal. Colonoscopy remains the reference standard for detection of precursor lesions, however, CT colonography is viable alternative for colorectal cancer screening. We recently performed a randomised population screening trial (COlonoscopy or CT COlonography for Screening; COCOS trial) to compare the yield of colonoscopy and CT colonography within the Netherlands. CT colonography had a significantly higher participation rate than colonoscopy and that for colonoscopy the yield for advanced adenomas was significantly higher than CT colonography, resulting in a comparable yield per invitee for both techniques.

However, during this trial only those participants with polyps of 10 mm and larger at CT colonography were referred for colonoscopy. When the largest polyp measured 6-9 mm at CT colonography, patients were advised to undergo surveillance CT colonography after 1.5 or 3 years, depending on the number of polyps. This policy was determined by the Dutch Health Council. The additional yield from the surveillance CT colonography will determine the final yield of a CT colonography screening program.

Within the COCOS trial experienced radiologic technicians and radiologists reported CT colonography with good accuracy results and therefore using technicians as observer may be a cost effective strategy.

The burden of a screening test is also important and in the COCOS trial somewhat higher than expected. However, the experienced burden may well differ in a second CT colonography.

Furthermore screening for cancer may cause relevant side effects. Especially waiting for screening follow-up and waiting for results may cause considerable negative psychological consequences and have to be weighed against CT colonography benefits.

In this study, 101 participants to the CT colonography arm of a randomized population-based screening trial (COCOS) who underwent CT colonography and in whom the largest lesion measured 6-9 mm, will be invited for a surveillance CT colonography by mail.

The primary outcome is the final CT colonography screening yield for advanced neoplasia per 100 invitees through determining surveillance CT colonography yield.

Secondary outcomes include:

1. Surveillance CT colonography participation;
2. Burden of awaiting surveillance CT colonography;
3. Pain and burden of surveillance CT colonography and compare this with the initial screening CT colonography;
4. Diagnostic performance of radiologists and technicians and to compare the performance.

This study will determine the final yield of a CT colonography population screening program.

## **Study design**

Surveillance CT colonography candidates will be invited by letter, three years after their initial screening (COCOS) CT colonography. In case of no response, a reminder letter is sent and if no response to the reminder letter, the person will be contacted by phone.

Burden of awaiting surveillance CT colonography is assessed with the pre-procedural questionnaire which is sent by mail within 4 weeks before the screening procedure.

Pain is assessed during the CT colonography insufflation procedure.

Pain and burden are assessed with a post-procedural questionnaire, which is sent by mail 14 days after the CT colonography.

## **Intervention**

1. Surveillance CT colonography;
2. Pre- and post- procedural questionnaires;
3. Pain assessment during CT colonography.

## Contacts

### **Public**

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## Eligibility criteria

### **Inclusion criteria**

Participants to the CT colonography arm of a randomized population screening trial (COCOS; NTR1829), who were advised to undergo surveillance CT colonography because their largest polyp measured 6-9mm.

### **Exclusion criteria**

1. Complete colonoscopy after initial screening CT colonography;
2. All 6-9mm lesions were removed after initial screening CT colonography (e.g. by colonoscopy or sigmoidoscopy).

## Study design

## Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	30-07-2012
Enrollment:	101
Type:	Actual

## Ethics review

Positive opinion	
Date:	31-07-2012
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	NL3406

<b>Register</b>	<b>ID</b>
NTR-old	NTR3549
Other	WBO- / VWS-number : 2009/03WBO / PG/OGZ 2.929.405 29;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A