

# Early diagnosis of colorectal cancer by faecal occult blood detection - the Goteborg trial

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 11/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 11/09/2007	<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

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## Additional identifiers

## Study information

**Scientific Title**

### **Study objectives**

By detection of early stages of colorectal tumours in the "healthy population", mortality from colorectal cancer is reduced.

Underlying this hypothesis is a further hypothesis that colorectal tumours develop over a time sequence, probably several years, from benign adenomas through localised cancer to cancer with spread growth, and that tumours in this sequence of development can be detected before they give symptoms observed by the individual.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approval received from the ethical committee of Goteborg University, Goteborg (Sweden) in 1982 (ref: 21-82).

### **Study design**

Randomised, controlled, single centre, population based, interventional trial; control group not invited for screening.

### **Primary study design**

Interventional

### **Study type(s)**

Screening

### **Health condition(s) or problem(s) studied**

Colorectal cancer

### **Interventions**

Intervention: detection of faecal blood by Haemoccult analyses of samples from three consecutive stools, in the group randomised to "screening"

Control: no contact/information

If blood was detected, there was a continued intervention involving consultation with colorectal surgeon, sigmoidoscopy (60 cm) and barium enema. If found at sigmoidoscopy, adenomas were removed. If cancer/suspected cancer found at either investigation, surgery was followed at earliest possible date.

Total duration of follow-up was 11 - 19 years, mean of 15 years.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

Mortality in colorectal cancer.

Time points were: after invitation, after screening participation, after work-up of positive screen test and after treatment for patients with positive work-up.

### **Key secondary outcome(s)**

1. Overall mortality
2. Quality of life
3. Sensitivity and specificity of screening procedure
4. Sensitivity and specificity of work up procedure
5. Stage distribution of adenomas and cancers

The questionnaires used were specifically designed for this trial, with face validation and tested in pilot populations before use. Time points were: after invitation, after screening participation, after work-up of positive screen test and after treatment for patients with positive work-up.

**Completion date**

31/12/2001

## Eligibility

**Key inclusion criteria**

The entire population was born between 1918 and 1931, men and women, in Goteborg, Sweden. Only those randomised to "intervention, i.e., screening for occult faecal blood" were invited to participate, the control group was not contacted. Initial invitation to the trial was when each individual was between the ages of 60 to 64 years, thus inclusion from 1982 to 1995 in cohorts of five years.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Key exclusion criteria**

Does not meet the above criteria.

**Date of first enrolment**

01/09/1982

**Date of final enrolment**

31/12/2001

## Locations

**Countries of recruitment**

Sweden

**Study participating centre**  
**Bruna Straket 11B**  
Goteborg  
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SE 413 45

## Sponsor information

**Organisation**  
Swedish Cancer Society (Sweden)

**ROR**  
<https://ror.org/0527jb766>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Swedish Cancer Society (Sweden)

**Alternative Name(s)**  
Swedish Cancer Society

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Trusts, charities, foundations (both public and private)

**Location**  
Sweden

**Funder Name**  
Assar Gabrielsson Foundation (Sweden)

**Funder Name**  
Goteborgs Lakarsallskap, Inga-Britt and Arne Lundberg Research Foundation (Sweden)

**Funder Name**

Magnus Bergvall Foundation (Sweden)

**Funder Name**

Gunnar and Elisabeth Nilsson Foundation (Sweden)

**Funder Name**

Jubileumsklinikens Foundation (Sweden)

**Funder Name**

Sahlgrenska University Hospital Foundation (Sweden)

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other publications</a>		01/12/1986		Yes	No
<a href="#">Other publications</a>		01/12/1987		Yes	No
<a href="#">Other publications</a>		01/08/1988		Yes	No
<a href="#">Other publications</a>		01/03/1989		Yes	No
<a href="#">Other publications</a>		01/03/1990		Yes	No
<a href="#">Other publications</a>	.	01/12/1990		Yes	No
<a href="#">Other publications</a>	.	12/06/1991		Yes	No
<a href="#">Other publications</a>	.	01/10/1992		Yes	No
<a href="#">Other publications</a>		01/02/1994		Yes	No
<a href="#">Other publications</a>		01/05/1994		Yes	No
<a href="#">Other publications</a>	.	01/02/1995		Yes	No
<a href="#">Other publications</a>	.	01/02/1995		Yes	No
<a href="#">Other publications</a>		01/06/1996		Yes	No
<a href="#">Other publications</a>		01/03/1997		Yes	No