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

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
16/08/2007		Protocol		
Registration date	Overall study status	Statistical analysis plan		
11/09/2007	Completed	Results		
<b>Last Edited</b> 11/09/2007	<b>Condition category</b> Cancer	Individual participant data		
		<ul><li>Record updated in last year</li></ul>		
11/03/2001	Caricer			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Prof Eva Haglind

#### Contact details

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# Additional identifiers

**Protocol serial number** N/A

# 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 Sweden 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?
Other publications		01/12/1986		Yes	No
Other publications		01/12/1987		Yes	No
Other publications		01/08/1988		Yes	No
Other publications		01/03/1989		Yes	No
Other publications		01/03/1990		Yes	No
Other publications	•	01/12/1990		Yes	No
Other publications	•	12/06/1991		Yes	No
Other publications	•	01/10/1992		Yes	No
Other publications		01/02/1994		Yes	No
Other publications		01/05/1994		Yes	No
Other publications	•	01/02/1995		Yes	No
Other publications	•	01/02/1995		Yes	No
Other publications		01/06/1996		Yes	No
Other publications		01/03/1997		Yes	No