

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

Submission date 16/08/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/09/2007	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/09/1982

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

Age group

Senior

Sex

Both

Target number of participants

68,000

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)

Sponsor details

David Bagares Gata 5

Stockholm

Sweden

SE 101 55

+46 (0)8 6771000

info@cancerfonden.se

Sponsor type

Research organisation

Website

<http://www.cancerfonden.se>

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

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

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