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

Submission date 16/08/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 11/09/2007	**Overall study status** Completed	
Last Edited 11/09/2007	**Condition category** Cancer	

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).

Primary study design
Interventional

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

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