







The Göteborg randomised population based prostate cancer screening trial

Submission date 22/06/2010	Recruitment status No longer recruiting	 Retrospectively registered
		 Protocol not yet added
Registration date 29/06/2010	Overall study status Completed	 SAP not yet added
		 Results added
Last Edited 13/09/2010	Condition category Cancer	 Raw data not yet added
		 Study completed

Plain English Summary

Not provided at time of registration

Study website

<http://media.erspc-media.org/sweden/>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Göteborg
Sweden
SE-41345

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number

N/A

Study information

Scientific Title

The Göteborg prostate cancer screening trial: a population-based randomised controlled trial of a screening group invited for biennial prostate specific antigen (PSA) testing versus a control group not invited

Study hypothesis

Prostate specific antigen (PSA) screening decreases prostate cancer mortality by 40% after 15 years.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Review Committee at the University of Göteborg approved in 1994

Study design

Population-based randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Condition

Prostate cancer

Interventions

Men allocated to the screening arm are invited every second year for PSA testing, until they reach the upper age limit (70 years). Only men with PSA at or above the threshold (greater than or equal to 3 ng/mL) are invited for further urological work-up including digital rectal examination (DRE), transrectal ultrasound (TRUS) examination, and laterally directed sextant biopsies.

Men allocated to the control group will not be part of any planned intervention; the incidence of prostate cancer, stage, grade and primary treatment as well as cause of death will be registered in the control group.

Last invitation to the study will be in 2014 but follow-up will continue for many more years. Last follow-up is not stated in the protocol as things may change during a 20-year study.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Prostate cancer specific mortality (absolute and relative risk reduction in cumulative prostate cancer mortality) analysed according to the intention-to-screen principle (comparing the screening group with the control group). Analysed at study completion (after 15 years).

Secondary outcome measures

1. Cumulative prostate cancer incidence and the proportion of screening attendees
2. Comparisons of stage and age distribution
3. Lead and length time bias
4. Quality of life between screened men and controls

Analysed at study completion.

Overall study start date

01/01/1995

Overall study end date

31/12/2014

Eligibility

Participant inclusion criteria

Men born during 1930 through 1944 living in the city of Göteborg, Sweden

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

20,000 randomised

Participant exclusion criteria

1. Men with a prior diagnosis of prostate cancer
2. Men who had died or emigrated but had not been removed from the Population Register at time of randomisation

Recruitment start date

01/01/1995

Recruitment end date

31/12/2014

Locations

Countries of recruitment

Sweden

Study participating centre

Bruna Stråket 11B

Göteborg

Sweden

SE-41345

Sponsor information

Organisation

Sahlgrenska University Hospital (Sweden)

Sponsor details

Östra

Göteborg

Sweden

SE-41345

Sponsor type

Hospital/treatment centre

Website

<http://www.sahlgrenska.se>

ROR

<https://ror.org/04vgqjj36>

Funder(s)

Funder type

Research organisation

Funder Name

Swedish Cancer Society (Sweden) (ref: 090107, 080315 and 083455)

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

Swedish Medical Research Council (Sweden) (ref: 20095)

Funder Name

National Cancer Institute (USA) (ref: R21-CA127768-01A1)

Alternative Name(s)

Instituto Nacional del Cáncer, NCI

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

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?
Results article	results	01/04/2004		Yes	No
Results article	results	01/09/2007		Yes	No
Results article	results	01/08/2010		Yes	No