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The Göteborg randomised population based prostate cancer screening trial

Submission date	Recruitment status	[ ] Prospectively registered
22/06/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/09/2010	Cancer	

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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 invitaion 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, National Cancer Institute at the National Institutes of Health, Instituto Nacional del Cáncer de los Institutos Nacionales de la Salud, 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