# The Göteborg randomised population based prostate cancer screening trial

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
22/06/2010		☐ 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 of protocol

Not provided at time of registration

## Study website

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

## Contact information

## Type(s)

Scientific

#### Contact name

Prof Jonas Hugosson

#### Contact details

Bruna Stråket 11B Göteborg Sweden SE-41345

## 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 objectives

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

## Health condition(s) or problem(s) studied

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

## Completion date

31/12/2014

## **Eligibility**

#### Key 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

## Key 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

## Date of first enrolment

01/01/1995

## Date of final enrolment

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)

National Cancer Institute at the National Institutes of Health, Instituto Nacional del Cáncer, 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