

# The Göteborg randomised population based prostate cancer screening trial

<b>Submission date</b> 22/06/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/09/2010	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Jonas Hugosson

**Contact details**  
Bruna Stråket 11B  
Göteborg  
Sweden  
SE-41345

## Additional identifiers

**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 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

### **Study type(s)**

Screening

### **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 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(s)**

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).

### **Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Male

**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)

## 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

### 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?
<a href="#">Results article</a>	results	01/04/2004		Yes	No
<a href="#">Results article</a>	results	01/09/2007		Yes	No
<a href="#">Results article</a>	results	01/08/2010		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes