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# The GÖTEBORG prostate cancer screening 2 trial

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 26/04/2017 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 10/07/2017 | Ongoing | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 26/09/2024 | Cancer | |

## Plain English summary of protocol

Background and study aims
Prostate cancer is the most common cancer among Swedish men, and Sweden has one of the highest prostate cancer mortality (death) rates in the world. 10,000 men are diagnosed with the disease each year and 2,400 die from it. Prostate-specific antigen (PSA) is a protein made by the prostate gland. A PSA test looks for raised levels of PSA in the blood which may be a sign of prostate cancer in its early stages. Screening with PSA testing can reduce prostate cancer mortality, but the major drawback is that many men are diagnosed with small insignificant tumours that would never cause neither disease nor death within the patient's lifetime (overdiagnosis). This dilemma is the main reason to why there is no public prostate cancer screening program for men. By using Magnetic Resonance Imaging (MRI) scans in men with high PSA in combination with targeted biopsies (tissue samples) of suspected tumours, screening could be more efficient and overdiagnosis might be reduced. The aim of this study is to find out whether prostate cancer screening with PSA followed by an MRI scan of the prostate reduces the risk of overdiagnosis.

Who can participate?
Men aged 50-60 from West Sweden

What does the study involve?
Participants are randomly allocated to either be invited for testing or not (control group). Men allocated to testing are randomly allocated in a second step into three groups. If their PSA level is normal, no further testing or examination is performed and the participant is re-invited for screening after 1, 2, 4 or 8 years depending on their PSA level. All men with high PSA, regardless of group, are offered an MRI scan of their prostate. If the MRI scan is positive, men from two of the groups are further examined with targeted biopsies. In the third group, standard biopsies are taken regardless of the MRI result. Rates of overdiagnosis, prostate biopsy and prostate cancer mortality are measured on a regular basis throughout the study using data from the Regional Cancer Registry.

What are the possible benefits and risks of participating?
The combination of PSA and MRI may improve prostate cancer diagnosis, reduce the number of men who need prostate biopsies, and reduce overdiagnosis and prostate cancer mortality. The possible risks are overdiagnosis and infection after the biopsy.

Where is the study run from?
University of Gothenburg/Sahlgrenska University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
September 2015 to December 2040

Who is funding the study?
1. Swedish Cancer Society (Sweden)
2. Swedish Government (Sweden)
3. BioCARE (Sweden)
4. Regional Cancer Center West (Sweden)
5. Swedish Research Council (Sweden)

Who is the main contact?
Prof. Jonas Hugosson

### Study website
http://g2screening.se/

# Contact information

### Type(s)
Scientific


### Contact name
Prof Jonas Hugosson

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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 2 trial (G2): a prospective, randomized, large-scale, population-based prostate cancer screening trial using PSA followed by magnetic resonance imaging of the prostate

### Study objectives
The study intends to analyze the value of PSA combined with Magnetic Resonance Tomography (MR) of the prostate for early detection of Prostate Cancer (PC). By using MR and only biopsying MR-positive men with targeted biopsies (in contrast to 10-12 systematic biopsies which is clinical practice today), the hypothesis is that overdiagnosis can be reduced by half and still keep the same sensitivity.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Regional Ethical Review Board, 28/01/2015, ref: 890-14

### Study design
Population-based randomized controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Screening

### Participant information sheet
See website (in Swedish)

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

### Interventions
By computerized randomization, a random sample of 40,000 men living in Västra Götalandsregionen will gradually be randomized and form the database. If a man decides to participate he visits a clinic to have a regular blood draw (PSA). The analysis of PSA is carried out

at a central lab. Men who choose to participate are randomized, by blinded computer randomization, in a 1:1:1 ratio (equal sizes) into three different screening strategies:

Arm 1: Reference arm: PSA cut-off 3 ng/mL, standard biopsies for all men with PSA >=3 plus targeted biopsies for MR+
“Screen-negative”: If the Total-PSA level is “normal”, i.e. below 3.0 ng/mL, no further testing or examination will be performed but all men will be re-invited (see below).
“Screen-positive”: If the PSA level is “elevated” above the cut-off i.e. 3.0 ng/mL, the man will be invited for a multi-parametric MRI (mpMRI). Irrespective of the MRI result all men will be recommended “STANDARD BIOPSY”, i.e. digital rectal exam followed by TRUS-guided 10-core standard prostate biopsy according to the screening protocol (as is also clinical practice). These standard biopsies will be taken blindly to the MRI result. During the same investigation after the standard biopsies the urologist will be shown the result from MRI and in case of a suspicious lesion at MRI also targeted biopsies (4 cores) will be added (same procedure as in the performed pilot study. The results from the reference arm could be divided into those detected by standard biopsy alone (pure PSA detected – common practice today) and those also detected by targeted biopsies (false negatives).

Arm 2: Experimental arm I: PSA cut-off 3 ng/mL, only targeted biopsies for MR+
“Screen-negative”: If the PSA level is “normal”, i.e. below 3.0 ng/mL, no further testing or examination will be performed. The man will be re-invited for screening identical to arm 1.
“Screen-positive”: If the PSA level is “elevated” ≥ 3.0 ng/mL, he will be offered mpMRI.
If the mpMRI is positive, only “TARGETED BIOPSIES” will be performed, i.e. 4 biopsy cores targeted against each suspicious lesion, but no systematic biopsies
If the mpMRI is negative, no biopsies will be performed.

Arm 3: Experimental arm II: PSA cut-off 1.8 ng/mL, only targeted biopsies for MR+
Identical to arm 2, except that the PSA-cut off is lower, 1.8 ng/mL.

Reinvitation (all arms):
The men will be re-invited to screening, with the interval length determined by the PSA level.

Reinvitation interval:
If PSA<0.6 ng/mL: 8-year interval
If PSA 0.6-1.2 ng/mL: 4-year interval
If PSA 1.2-2.4 ng/mL: 2-year interval
If PSA 2.4-3.0 ng/mL: 1-year interval

Regardless of age at first invitation all men will be invited twice, thereafter the following upper age limits for participation in combination with PSA values will be used:
If PSA <0.51 ng/mL: age 62
If PSA 0.51-1.00 ng/mL: age 65
If PSA 1.01-1.80 ng/mL: age 70
Non responder: age 70
Irrespective: age 75

## Intervention Type
Other

## Primary outcome measure
Rate of overdiagnosis, measured by linking the study population/study database with the Regional Cancer Registry every third month until the study ends

### Secondary outcome measures
Rate of prostate biopsy, defined as the number of events per randomized men measured continuously throughout the study

Tertiary outcome measure:
Prostate cancer mortality, measured by linkage with the Swedish Causes of Death Registry twice a year until the study ends

### Overall study start date
01/09/2015

### Completion date
31/12/2040

## Eligibility

### Key inclusion criteria
1. Male
2. Age 50-60
3. Living in selected municipalities in Västra Götaland, Sweden

### Participant type(s)
All

### Age group
Adult

### Sex
Male

### Target number of participants
40,000

### Total final enrolment
17980

### Key exclusion criteria
Men with prior diagnosis of prostate cancer

### Date of first enrolment
01/09/2015

### Date of final enrolment
30/06/2020

## Locations

### Countries of recruitment
Sweden

**Study participating centre**
**University of Gothenburg/Sahlgrenska University Hospital**
Departments of Urology and Radiology
Bruna stråket 11B
Göteborg
Sweden
41345

# Sponsor information

**Organisation**
University of Gothenburg

**Sponsor details**
Box 100
Göteborg
Sweden
405 30

**Sponsor type**
University/education

**Website**
http://www.gu.se/

**ROR**
https://ror.org/01tm6cn81

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
Cancerfonden

**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 Government

**Funder Name**
Biocare

**Funder Name**
Regional Cancer Center West

**Funder Name**
Vetenskapsrådet

**Alternative Name(s)**
Swedish Research Council, VR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
Sweden

# Results and Publications

**Publication and dissemination plan**
Primary outcome is planned to be published in Autumn 2020.

**Intention to publish date**
01/09/2020

**Individual participant data (IPD) sharing plan**

The current data sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | primary and secondary outcome results | 08/12/2022 | 12/12/2022 | Yes | No |
| Results article | Four-year results | 26/09/2024 | 26/09/2024 | Yes | No |