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STHLM3 - Prostate cancer diagnostic trial

Submission date 14/11/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 03/01/2013	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 04/10/2022	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Prostate cancer is a leading cause of cancer death among men in the Western world. A PSA test looks for raised levels of PSA in the blood that may be a sign of prostate cancer in its early stages. Although PSA screening has been shown to prevent deaths, it can also lead to over-diagnosis (diagnosis of disease that would not have caused symptoms or death) and performing unnecessary biopsies (where a sample of the prostate is taken for diagnosis). The aim of this study is to assess whether a new biomarker test for prostate cancer can reduce how many men are referred to biopsy whilst still detecting high-risk prostate cancer. The study will also assess whether the new test decreases the number of low-risk prostate cancers diagnosed and improves the quality and effectiveness of prostate cancer diagnosis in routine health care in Stockholm.

Who can participate?
Men aged 50 to 69 living in Stockholm County Council or Region Gotland who have not previously been diagnosed with prostate cancer

What does the study involve?
Participants are randomly allocated to one of two groups. One group are referred to biopsy based on the PSA test result only. The other group are referred to biopsy based on their age, their genes, their family history and biomarkers.

What are the possible benefits and risks of participating?
There are no benefits for the participants other than a free prostate cancer test. There is a low risk of over-diagnosis of low-risk cancers.

Where is the study run from?
Karolinska Institutet (Sweden)

When is the study starting and how long is it expected to run for?
January 2013 to December 2014

Who is funding the study?
Stockholm County Council (Sweden)

Who is the main contact?
Prof. Henrik Grönberg

Study website
http://sthlm3.se

Contact information

Type(s)
Scientific

Contact name
Prof Henrik Grönberg

Contact details
Nobels väg 12
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17177

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
STHLM3 - Prostate cancer diagnostic randomized trial

Acronym
STHLM3

Study objectives
STHLM3 [STHLM relates to the city of Stockholm, Number 3 relates to that this is the third study within the same setting] is a randomized controlled trial aiming to assess whether a panel of biomarkers for prostate cancer can substantially reduce the proportion of men referred to biopsy whilst maintaining sensitivity for high risk prostate cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Stockholm Ethical Review Board, 09/05/2012, ref: r DNR 2012/572-31/1

Study design
Two-armed randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Patient information in Swedish can be found at http://sthlm3.se/dokument/

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

Interventions
The two study arms will be:

Control/PSA arm, where referral to biopsy will be based on Prostate-specific antigen (PSA) only with PSA ≥ 3 as the level of referral to prostate biopsy

Intervention/Best biomarker panel (BBP) arm, where referral to biopsy will be determined by a risk prediction model based on age, an array of single-nucleotide polymorphism (SNPs), family history and protein-based biomarkers.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To increase the specificity of a combined prostate cancer test compared to the PSA test without decreasing the sensitivity of high risk of prostate cancers (defined as Gleason 7 or higher). The primary endpoint is number of prostate biopsies.

Secondary outcome measures
1. To decrease the number of low risk prostate cancers diagnosed
2. To increase the health related quality of life and knowledge of prostate cancer testing
3. To assess the health economic consequences of implementing prostate cancer screening
4. To improve the quality and effectiveness of prostate cancer diagnosis in the routine health care in Stockholm
5. To assess the overall long-term mortality of prostate cancer in the Stockholm/Gotland area

over a 10-15 year period
6. To assess the combination of a blood based best biomarker panel and urine biomarkers in men with initial negative prostate biopsy (separate study protocol STHLM3-Rebiopsy) and
7. To facilitate inclusion in active surveillance protocol in men diagnosed with low risk prostate cancers

Overall study start date
01/01/2013

Completion date
31/12/2014

Eligibility

Key inclusion criteria
All men between 50 and 69 years of age who have a permanent postal address in Stockholm County Council or Region Gotland (N=260,000) will be asked whether they would like to take part in STHLM3.

Participant type(s)
All

Age group
Adult

Sex
Male

Target number of participants
140,000

Key exclusion criteria
Diagnosed with prostate cancer

Date of first enrolment
01/01/2013

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Sweden

Study participating centre
Nobels väg 12
Stockholm

Sweden
17177

Sponsor information

Organisation
Karolinska Institutet (Sweden)

Sponsor details
Department of Medical Epidemiology and Biostatistics
PO Box 281
Stockholm
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17177

Sponsor type
Research organisation

Website
http://ki.se/ki/jsp/polopoly.jsp?l=en&d=9600

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Government

Funder Name
Stockholm County Council (Sweden)

Alternative Name(s)
Stockholm County Council

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/12/2015		Yes	No
Results article		29/08/2022	04/10/2022	Yes	No