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Prostate disease Screening Program in Novohopersk area of Voronezh region ("Novohopersk")

Submission date
26/08/2014

Recruitment status
No longer recruiting

Registration date
22/09/2014

Overall study status
Completed

Last Edited
29/05/2020

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Prostate cancer in men is very common. However, it usually develops slowly with the first signs of the disease being problems with urinating once the prostate is large enough to press against the urethra (the tube that takes urine from the bladder to the penis). If caught early, this form of cancer is very treatable and many countries have screening programmes to detect it. Early stage prostate cancer can be diagnosed using a blood test called the prostate-specific antigen (PSA) test. An increased amount of PSA can, in some cases, happen due to prostate cancer. In Russia, the number of men with prostate cancer is rather high, is increasing and has a high mortality rate (high number of men dying from the disease). The high mortality rate is a result of a large number of cases not being diagnosed until the disease is at an advanced stage and has already spread to other parts of the body. A PSA test cannot be used to definitely detect the condition as it can also be raised due to, for example, non-cancerous growths and urinary tract diseases. However, Russia healthcare services do need a method to detect prostate cancer earlier. Here, we are going to look at how possible it is to have a PSA test screening programme in Russia, how well it would perform and whether it would be worth spending money on such a programme. We want to estimate how many men in a particular region have the disease, at what stage the cancer is detected and how useful a PSA test might be in screening for the disease, particularly for men aged 45-54 (as this age group is less likely to be included in PSA screening programmes). We also want to calculate how much a screening programme would cost and whether it would be worth the money involved, taking into account the relatively short male life expectancy in Russia.

Who can participate?
Men aged 45-65 in the Novohopersk area of the Voronezh Region (VO)

What does the study involve?
After gathering clinical information for all the participants (from the state medical compulsory insurance system), they are invited for a PSA test at a study centre. They then have a physical examination to check for prostate cancer and undergo a transrectal ultrasound scan (TRUS) to see how large the prostate gland is. In those cases where prostate cancer is found, the affected

participants undergo further tests to see how far the cancer has progressed (pelvic MRI, bone scintigraphy and possible abdominal, peritoneal and thoracic CT scans).

What are the possible benefits and risks of participating?
The major benefits to participants taking part in the study are a high quality medical examination and early detection of prostate cancer. The risks involve infections and other complications and side-effects of biopsy.

Where is the study run from?
1. Federal State Research Scientific Institute of Urology of the Health Ministry of Russia (Russia)
2. Healthcare Department of Voronezh Region (Russia)
3. MBHI Novohapersk Central Regional Hospital (Russia)
4. VO BHI Voronezh Regional Clinical Hospital N1 (Russia)

When is the study starting and how long is it expected to run for?
December 2013 to January 2015.

Who is funding the study?
1. Federal State Research Scientific Institute of Urology of the Health Ministry of Russia (Russia)
2. Healthcare Department of Voronezh Region (Russia)
3. MBHI Novohapersk Central Regional Hospital (Russia)
4. VO BHI Voronezh Regional Clinical Hospital N1 (Russia)
5. LLC Beckman Coulter (Russia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Population-based screening study: feasibility and effects evaluation of prostate cancer (PCa) screening in Russia and evaluation of economic efficacy

Acronym
SPiNAV

Study objectives
It is hypothesized that screening decreases mortality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethical committee, 28/10/2013, ref. N98

Study design
12-months population-based study

Primary study design
Interventional

Secondary study design
Single-centre

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the following contact details to request a patient information sheet: Federal State Budget Scientific Research Institute of Urology, Ministry of Health Care of Russian Federation, Moscow 105425 3d Parkovaya 51, phone +7 499 367 75 87, email: apolikhin.oleg@gmail.com or international.uro@gmail.com

Health condition(s) or problem(s) studied
Prostate disease/prostate cancer

Interventions
1. All involved patients fill questionnaires (IPSS/QoL, SWOP - calculator 1,2 and 4)
2. Blood serum PSA level detection
3. Digital rectal examination (DRE)

4. Transrectal ultrasound scan (TRUS)
5. Pelvic MRI (1 month after prostate biopsy)
6. Bone scintigraphy (PSA level ≥ 20 ng/ml)
7. Thorax CT, X ray
8. Abdominal, peritoneal and thoracic CT scan (by indications)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Prostate cancer detection rate (%)
2. Prostate cancer detection rate in age groups (%)
3. Prostate cancer detection rate by stages (TNM system)
4. PSA sensitivity, specificity, PPV and NPV (%)
5. Prostate cancer detection costs in one patient in rubles
6. Localized clinically significant (treatment needed) prostate cancer detection costs in one patient in rubles

Secondary outcome measures
1. Questionnaires (IPSS/QoL, SWOP calculator 1,2 and 4) - results registered in points and percents
2. Blood serum PSA level detection (PSA) - ng/ml
3. Digital rectal examination (DRE) - positive/negative
4. Transrectal ultrasound scan (TRUS), (positive/negative) including determination of prostate volume in cc
5. Prostate biopsy (standard 12 core) with morphological examination of tissue samples
6. Cancer staging - registered in TNM system

Overall study start date
01/12/2013

Completion date
01/01/2015

Eligibility

Key inclusion criteria
Men aged 45-65

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
3715

Key exclusion criteria
Prostate cancer in anamnesis

Date of first enrolment
01/12/2013

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
Russian Federation

Study participating centre
3d Parkovaya str
Moscow
Russian Federation
105425

Sponsor information

Organisation
Federal State Research Institute of Urology of Ministry of Health Care of Russia (Russia)

Sponsor details
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Sponsor type
Government

Website
http://uro.ru

ROR
https://ror.org/01p8ehb87

Funder(s)

Funder type
Other

Funder Name
Federal State Research Institute of Urology of the Ministry of Health Care of Russia, Moscow (Russia)

Funder Name
Healthcare Department of Voronezh Region (Russia)

Funder Name
MBHI Novohapersk Central Regional Hospital (Russia)

Funder Name
VO BHI Voronezh Regional clinical hospital N1 (Russia)

Funder Name
LLC Beckman Coulter (Russia)

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