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Pilot programme for lung cancer screening in Belarus

Submission date	Recruitment status	[X] Prospectively registered
13/08/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/09/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/09/2020	Cancer	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Lung cancer is the most commonly diagnosed cancer among men in Belarus. It is also the most frequent cause of cancer death among men in Belarus; 40% of the adult male population are smokers.
The purpose of this research is to evaluate a pilot program for lung cancer screening in Belarus. Lung cancer screening differs from the other currently recommended programmes in that it specifically targets people at high-risk.

Who can participate?
Men aged 50 to 70 years old at high risk of lung cancer.

What does the study involve?
A risk prediction model will calculate an individual's risk based on age and smoking history. If this pre-selection questionnaire indicates that the individual is eligible, the participant will undergo low-dose computed tomography of chest organs annually for 3 years and be followed-up for an extra 2 years.

What are the possible benefits and risks of participating?
The individual have a benefit in participating in the study, which consists of better lung cancer survival as the tumour might be detected at an early clinical stage. There are some possible harms also related to participating in the study, regarding undergoing lung cancer screening using low-dose computed tomography, those include the risk of false-positive result, over-diagnosis, and psychological discomfort.

Where is the study run from?
N.N. Alexandrov National Cancer Centre of Belarus

When is the study starting and how long is it expected to run for?
July 2019 to December 2024

Who is funding the study?
This research is funded by the Belarus Government

Who is the main contact?
Andre Carvalho, carvalhoa@iarc.fr

Contact information

Type(s)
Scientific

Contact name
Dr Andre Carvalho

ORCID ID
https://orcid.org/0000-0001-7214-6402

Contact details
International Agency for Research on Cancer
World Health Organization
150 cours Albert Thomas
Lyon
France
69372
+33 472738599
carvalhoa@iarc.fr

Type(s)
Public

Contact name
Dr Olga Trusova

Contact details
N.N. Alexandrov National Cancer Centre of Belarus
Lesnoy 2
Minsk District
Minsk Region
Belarus
223040
+375 17 265 39 52
o.trusova@tut.by

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ICE 19-40

Study information

Scientific Title
Development and implementation of a pilot programme for lung cancer screening in Belarus

Acronym
BELUNGS

Study objectives
Lung cancer is the most commonly diagnosed cancer among men and the most frequent cause of cancer mortality in Belarus while the prevalence of smoking remains unacceptably high. Lung cancer screening by low-dose CT has now been shown by multiple randomized trials to reduce lung cancer deaths. WHO does not currently recommend population-based lung cancer screening, but the rapid movement toward its implementation represents an opportunity for research projects evaluating knowledge gaps and generate new evidence, particularly in settings where resources are limited. The purpose of this research was to evaluate the development and implementation of a pilot program for a low-dose CT lung cancer screening in Belarus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 13/02/2020, IARC Ethics Committee (IARC Ethics Committee: 150 cours Albert Thomas, 69372 Lyon cedex 08, France; +33 (0)4 72 73 83 41; iec-secretariat@iarc.fr), ref IEC 19-40
2. Approved 23/09/2019, the Academic Council meeting (N.N. Alexandrov National Cancer Center of Belarus: 223040 Lesnoy, Minsk District, Republic of Belarus; +375 17 265 39 52; o. trusova@tut.by), ref: 23.09.2019 №14

Study design
Observational prospective cohort study

Primary study design
Observational

Study type(s)
Screening

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

Interventions
Age-appropriate men will be identified from a population list serviced by medical institutions participating in the project. Identified participants with respond to a pre-selection questionnaire sent by mail or answered during a regular visit to the medical institution. Individuals will be selected for LDCT lung cancer screening based on the information provided to the pre-selection questionnaire, after considering a risk-based approach. Also, other inclusion and exclusion criteria should be considered before proposing individuals to participate in the study. Invited individuals will get clarifications regarding the purpose of the study and the study's procedures by trained recruiters. Recruiters will also explain the inform consent form and answer to any

concerns/doubts of the individual regarding their participation in the study. Participant inclusion at the study will only happen after all doubts and concerns have been addressed, and the inform consent form has been signed.
A total of 3,000 participants is planned to be enrolled in the project, 1,000 from each district. Eligible participants will undergo low-dose computed tomography of chest organs annually for the first 3 years and shall be monitored and followed in the project for 5 years. Blood samples will be collected, processed and storage in a biorepository for a possible future research on biomarkers. All scans will be read by 2 independent radiologists. The British Thoracic Society guidelines for the investigation and management of pulmonary nodules will be adopted in this project. Data from the epidemiological questionnaire, the LDCT findings, clinical management of the findings and medical records for the cancer detected cases will be registered, collected and analysed.

Intervention Type
Other

Primary outcome(s)
1. The clinical-stage distribution of lung cancer using low-dose CT scan at a single time point
2. Number of cases eligible for radical surgical procedure measured using clinical and radiological evaluation over the duration of the study

Key secondary outcome(s))
1. Number of invited individuals selected for LDCT screening according to the proposed risk-based approach, measured by the pre-selection questionnaire responses throughout the study
2. Radiological findings of the LDCT: number of participants with nodules, the characteristic of the nodules and accuracy of the radiological findings with the pathology report (for participants undergoing biopsy) measured at a single time point
3. Concordance of radiological findings among the radiologists involved in the project, by Cohen's kappa coefficient analysis measured throughout the study
3. Document and monitor the harms of the LDCT screening, recorded in the study questionnaires and medical records, throughout the study

Completion date
02/12/2024

Eligibility

Key inclusion criteria
1. Availability of written informed consent
2. Age from 50 through 70 years
3. Risk-based approach a 5-year lung cancer risk of at least 1.51% (using the Lung Cancer Risk Assessment Tool)
4. No advanced chronic lung diseases
5. No advanced occupational hazard conditions
6. A clinical-functional status allowing the possibility to administer surgical treatment

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Upper age limit
70 years

Sex
Male

Key exclusion criteria
1. Second primaries of synchronous and metachronous cancer of both lungs or a combination of lung cancer with cancer of other organs excluding uterine cervix cancer, non-melanoma skin cancer, and lower lip cancer radically treated at least 3 years ago
2. Previous special treatment for lung cancer
3. Acute tuberculosis
4. Myocardial infarction, stroke in the case history in the course the past 6 months before enrolling in the study

Criteria for excluding from the study, based on examination findings:
1. Congestive heart failure, class III or IV according to NYHA (New York Heart Association) classification, unrelated to the neoplastic process
2. Uncontrolled severe hypertension or hypertension with systolic pressure >180 mm Hg and/or diastolic pressure >110 mm Hg, or orthostatic hypotension
3. A positive test for human immunodeficiency virus (HIV), B or C hepatitis, or lues
4. Mental diseases
5. Chronic alcohol addiction
6. Surd mutism

Administrative causes for exclusion from the study:
1. Kinship relations between the patient and the Centre’s employers
2. The inability of visits/procedure performance and regular medical check-up
3. Refusal to undergo examination or treatment in the course of the study

Date of first enrolment
01/10/2020

Date of final enrolment
01/12/2024

Locations

Countries of recruitment
Belarus

Study participating centre

N.N. Alexandrov National Cancer Centre of Belarus
223040 Lesnoy
Minsk District
Minsk Region
Belarus
223040

Study participating centre
Minsk Central District Hospital
1, Frunzenskaya str
Minsk district
Minsk region
Belarus
223053

Study participating centre
Soligorsk Central District Hospital
1 Korzh str
Soligorsk
Minsk region
Belarus
223710

Study participating centre
Grodno University hospital
52, boulevard of Lenin Komsomol
Grodno
Belarus
230009

Study participating centre
Minsk Regional Tuberculosis dispensary
village Leskovka
Minsk district
Minsk region
Belarus
223058

Study participating centre
Vilejka Central District hospital
27, Markov str

Vilejka
Minsk region
Belarus
222416

Sponsor information

Organisation
N.N. Alexandrov National Cancer Centre

ROR
https://ror.org/03ceh9q73

Organisation
International Agency For Research On Cancer

ROR
https://ror.org/00v452281

Funder(s)

Funder type
Government

Funder Name
Federal Government of the Republic of Belarus

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date