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Multicentric pilot programme for lung cancer screening

Submission date	Recruitment status	[ ] Prospectively registered
18/03/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/05/2024	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/08/2026	Cancer	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Worldwide, lung cancer is the second most common cancer (11.4% of new cases) and the first cause of cancer deaths (18%). In 2000, 50% of men and 16.7% of women aged 15 years and older were current users of some form of tobacco. By 2015, the proportions had declined to 40.3% and 9.5%, respectively. By 2025, the rate is projected to decline to 35.1% among men and 6.7% among women.

The aim of this study is to evaluate a multicentre pilot program for lung cancer screening. Lung cancer screening differs from the other currently recommended programmes in that it specifically targets people at high risk.

Who can participate?

Men and women aged 50 to 74 years old who are 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 (LDCT) 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 has 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 LDCT, those include the risk of false-positive results, over-diagnosis, and psychological discomfort.

Where is the study run from?

1. National Cancer Control Programme (PRONACCAN) (Uruguay)
2. Thoracic Surgery Service, Thoracic Institute of Hospital Maciel, ASSE (Uruguay)

When is the study starting and how long is it expected to run for?

October 2019 to December 2032

Who is funding the study?
1. PRONACCAN, Ministry of Health (Uruguay)
2. State Health Services Administration (ASSE) (Uruguay)

Who is the main contact?
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Additional identifiers

Protocol serial number
IEC 19-40

Study information

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

Acronym
UY-LUNGS

Study objectives
Worldwide, lung cancer is the second most incident cancer (11.4% of new cases) and the first cause of cancer mortality (18%), while the prevalence of smoking remains unacceptably high. Lung cancer screening by low-dose computed tomography (LDCT) has now been shown by multiple randomized trials to reduce lung cancer deaths. The WHO does not currently recommend population-based lung cancer screening, but the rapid movement toward its implementation represents an opportunity for research projects to evaluate 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 low-dose computed tomography (CT) lung cancer screening in several countries.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 13/02/2020, IARC Ethics Committee (150 cours Albert Thomas, Lyon, 69372, France; +33 (0)4 72 73 83 41; iec-secretariat@iarc.fr), ref: IEC 19-40

2. Approved 19/10/2022, The Research Ethics Committee of Hospital Maciel (CEIHM) meeting (25 de Mayo 174, Montevideo, 11000, Uruguay; +598 (0)2915 3000; comitedeeticahm@outlook.com), ref: Nº32

3. Approved 07/11/2022, Research Bioethics Committee of INCA meeting (Joanicó 3265, Montevideo, 11000, Uruguay; +598 (0)2481 2040; comiteetica.inca@gmail.com), ref: P2022/05

Primary study design
Observational

Study design
Observational prospective cohort study

Study type(s)
Screening

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

Interventions
Age-appropriate men and women will be identified from a population list serviced by medical institutions participating in the project. Identified participants will respond to a pre-selection questionnaire sent by phone or SMS. Individuals will be selected for low-dose computed tomography (LDCT) lung cancer screening based on the information provided in 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 informed consent form and answer any concerns/doubts of the individual regarding their participation in the study. Participant inclusion in the study will only happen after all doubts and concerns have been addressed, and the informed consent form has been signed.

Eligible participants will undergo LDCT of chest organs annually for the first 3 years and shall be monitored and followed in the project for 5 years. All scans will be read by two radiologists. The Lung CT Screening Reporting and Data System (Lung-RADS) tool 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 with low-dose computed tomography (CT) scan using TNM classification at 12, 24, 48 and 60 months
2. Number of cases eligible for radical surgical procedure measured using clinical and radiological evaluation at 12, 24, 48 and 60 months
3. Cost-effectiveness analysis at 60 months. The modelling methodology will allow the researchers to scale costs and outcomes appropriately to the national level using consistent methods. In addition, without estimates of the long-term impact from mathematical modelling, the analysis could be misleading to decision-makers by focusing only on the short-term impact of screening.
Aim 1: To align the health economic modelling with the contents of the Statistical Analysis Plan (SAP). The SAP objectives to estimate the number of scans per cancer detected and to estimate the short-term impact of screening on early cancer detection and lung cancer mortality will tie in with Objective 1.
Objective 1: Estimate the cost per cancer detected within a potential national lung cancer screening programme in the short term.
Aim 2: Use modelling methodology to predict the cost-effectiveness, long-term budget impact and return-on-investment of a potential national lung cancer screening programme.
Objective 2: Predict the long-term clinical impact of screening within a potential national lung cancer screening programme.
Objective 3: Predict the long-term budget impact and return-on-investment of a potential national lung cancer screening programme.

Key secondary outcome(s)
1. Number of invited individuals selected for low-dose computed tomography (LDCT) screening according to the proposed risk-based approach, measured by the pre-selection questionnaire responses at 12, 24 and 36 months
2. Radiological findings of the LDCT: the number of participants with nodules, the characteristics of the nodules and the accuracy of the radiological findings with the pathology report (for participants undergoing biopsy) measured at 12, 24, 48 and 60 months
3. The harms of the LDCT screening, recorded in study questionnaires and medical records at 12, 24, 48 and 60 months

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Availability of written informed consent
2. Aged 50 to 74 years
3. 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
74 Years

Sex
All

Total final enrolment
175

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 treatment for lung cancer
3. Acute tuberculosis
4. Myocardial infarction, stroke in the case history in the course of 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 New York Heart Association (NYHA) classification, unrelated to the neoplastic process
2. Uncontrolled severe hypertension or hypertension with systolic pressure >180 mmHg and/or diastolic pressure >110 mmHg, 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-ups
3. Refusal to undergo examination or treatment in the course of the study

Date of first enrolment
18/05/2023

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Uruguay

Study participating centre
Hospital Maciel
25 de Mayo 174
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Study participating centre
Instituto Nacional del Cáncer
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11000

Sponsor information

Organisation
National Cancer Control Programme (PRONACCAN) of Uruguay

Organisation
International Agency For Research On Cancer

ROR
https://ror.org/00v452281

Funder(s)

Funder type
Government

Funder Name
National Cancer Control Programme (PRONACCAN) of Uruguay

Results and Publications

Individual participant data (IPD) sharing plan

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