NEW YORK FEMALE ASIAN NONSMOKER SCREENING STUDY (FANSS): EXPLORING LUNG CANCER SCREENING IN A HIGH RISK POPULATION

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BACKGROUND

• Lung cancer is the leading cause of cancer death in Asian Americans and unfortunately the majority are diagnosed at advanced or late stage lung cancers.
• It has been reported that about 32% of Asians who have lung cancer do not smoke. In Asia, approximately 60 to 80% of female lung cancer patients are never smokers. In Taiwan, 55% of lung cancers are in never smokers and over 90% of the female lung cancer patients are never smokers.
• In comparison to patients diagnosed with locally advanced or metastatic lung cancer, patients with stage I lung cancers have higher cure and survival rates, supporting the premise of lung cancer screening programs.
• However, lung cancer screening has been focused on high risk populations that include current smokers or former smokers with an at least 30 pack year smoking history.
• NYFANSS is a study to develop a database and biorepository of Asian female never smokers residing in New York who undergo a low-dose CT (LDCT) scan for lung cancer screening.

OBJECTIVES

• The primary objective of this study is to develop a database of clinical, demographic and radiographic data in Asian female never smokers who reside in New York who participate in a lung cancer screening program.
• The feasibility of a lung cancer screening program in Asian female nonsmokers will be evaluated by determining the number of subjects who inquire about the program and are eligible to proceed with the LDCT screening test.
• The rates of eligible patients who undergo the initial LDCT and subsequent screens will be estimated to determine adherence to screening.
• The primary endpoint for each subject will be whether or not the subject underwent the initial LDCT.
• Secondary endpoints for each subject include: diagnosis of lung cancer, detection of incidental thyroid nodules, and detection of incidental coronary artery disease on initial screen, and on subsequent screens.
• Exploratory objectives include identification of potential predictive biomarkers of malignancy in this Asian, female, never smoker population.

STUDY DESIGN

Prior to Enrollment

• Obtain informed consent.
• Screen potential patients by inclusion and exclusion criteria.

Enrollment (Baseline) Visit

• Verify inclusion and exclusion criteria.
• Conduct shared decision making conversation regarding risks and benefits of low dose CT scan (LDCT).
• Schedule a LDCT exam within 30 days.
• Administer questionnaire.
• Obtain blood specimen for Delfi Diagnostics assay.

Followup of Results (Visit 2)

• Review LDCT exam result #1.
• Refer for further workup if applicable.

Annual Followup

• Record any new history, exam.
• Schedule a LDCT exam within 30 days.
• Obtain blood specimen for Delfi Diagnostics assay.

Annual Results Followup (Year 2, 3)

• Review LDCT exam result #2, and if applicable a year later result #3.
• Refer for further workup if applicable.

STUDY PROCEDURES

• Low-dose computed tomography (LDCT) scans will be performed at baseline and annually at Years 1 and 2 for all subjects on the study.
• Delfi Diagnostics has developed an approach called “DNA evaluation of fragments for early interceptions” (DELFi) to detect a large number of abnormalities in cfDNA by genome-wide analysis of fragmentation patterns. They recently applied DELFi to analyze the fragmentation profiles of 230 patients with breast, colon/rectal, lung, ovarian, pancreatic, gastric or bile duct cancer and 245 healthy individuals. A machine learning model using these fragmentation profiles had sensitivities of detection ranging from 57% to more than 99% among the seven cancer types at 98% specificity, with an overall area under the curve value of 0.94. In 75% of the cases, the tissue of origin of the cancer could be identified in a limited number of sites.
• A questionnaire regarding demographic info, medical history, environmental exposures, and WTC exposure will be administered.

ELIGIBILITY CRITERIA

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Age 40-74 years.
2. Female
3. Never Smoker defined as a lifetime exposure of less than 100 cigarettes.
4. Identify at from Asian descent, defined as having reported ancestry or race from the continent of Asia. Individuals with mixed heritage are eligible.
5. Reside in the New York metropolitan area which for this study is defined as New York City (including the 5 boroughs: Manhattan, Brooklyn, Queens, Bronx, Staten Island) and Long Island.

An individual who meets any of the following criteria will be excluded from participation in this study:

2. Treatment for, or advisement by a physician of evidence of any cancer within the past five years, with the exceptions of non-melanoma skin cancer and most in-situ carcinomas based on PI discretion. (Treatment for, or evidence of, melanoma or in-situ bladder/transition cell carcinomas within the preceding five years renders the potential participant ineligible.)
3. Participation in a cancer prevention trial.
4. Present symptoms suggestive of current lung cancer, including: unexplained weight loss of over 15 pounds within the last 12 months or unexplained hemoptysis.
5. Medical or psychiatric condition precluding informed medical consent.
6. Pneumonia or acute respiratory infection within 12 weeks of enrollment that was treated with antibiotics under physician supervision.

CONCLUSIONS

The reported increased incidence of lung cancer in Asian female nonsmokers suggests this is a high risk population for the development of lung cancer. As a result, a lung screening program for this population has the potential to impact current clinical guidelines.

FOR MORE INFORMATION

• Interested participants, referring physicians or for more info, please call (212) 731-6212 or
• Email: elaine.shum@nyulangone.org