

EP04.14: Earlier Detection of Lung Cancer With Liquid Biopsy in Patients With Solitary Pulmonary Nodules and Ground-Glass Opacities

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INTRODUCTION

- Despite the rapid advancement of targeted agents and immunotherapy, lung cancer remains one of the leading cause of cancer-related mortality worldwide.
- Efforts towards **early detection** of the lung cancer offering curative therapies could improve outcomes by reducing recurrences and better quality of life.
- Currently, **low-dose computed tomography (LDCT)** is strongly recommended for individuals between ages 54 to 74 and smoking history but compliance remains low (~39%).
- In patients with **solitary pulmonary nodule (SPN)** and/or **ground glass opacity (GGO)** despite higher chances of lung cancer detection, follow-up protocols vary significantly across institutions.
- Liquid biopsy's** application has been largely limited to advanced stages for molecular profiling but it has potential to **improve cancer screening compliance and improve sensitivity over current screening tools.**

ELIGIBILITY CRITERIA

Main Inclusion Criteria

- Risk of lung cancer defined by smoking history of **at least 20 pack-year smoking history** and currently smoking or have quit within the past 15 years
- Only **1 lesion (>8mm solid, semi-solid or GGO)** detected with low dose-chest CT scan or contrast-enhanced chest CT
- Requires radiological evaluation**, including PET-CT, brain MRI
- Able to undergo surgical resection and provide information on the final pathologic diagnosis
- Able to complete all screening procedures within the 60-day screening window
- Willing and able to provide informed consent and follow-up period per protocol
- ≥50 years** of age
- ECOG performance status of 0 or 1
- Adequate organ function to complete all radiologic and pathologic evaluations

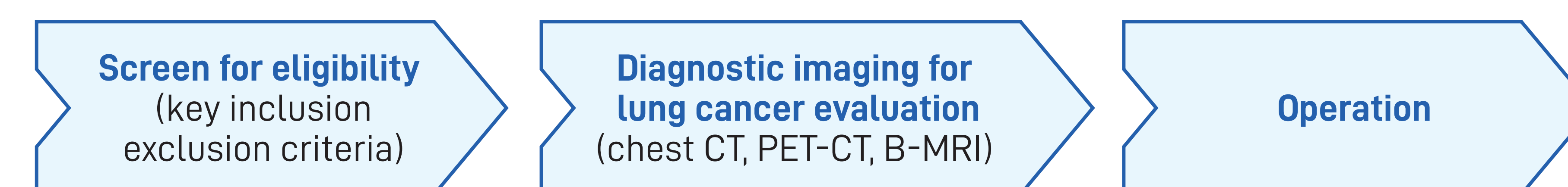
Main Exclusion Criteria

- Histologically-or cytological-confirmed diagnosis of lung cancer (such as squamous or non-squamous NSCLC and SCLC)
- Histologically-or cytological-confirmed diagnosis of any solid or hematological malignancy
- Active infection requiring antibiotics, antifungal or antiviral agents within 8 weeks
- Active autoimmune disease that has required systemic treatment in the past 5 years

TRIAL DESIGN

- EARLY is a single-center, prospective observational cohort study evaluating performance of Guardant Shield test in 50 patients with SPN and GGO in detecting lung cancer.
- Single time point blood collection before surgery is being carried out for retrospective analysis to correlate the Shield results with findings of the surgical specimen.
- Shield testing is supported by Guardant Health. (Shield test for lung cancer is an investigational test)
- The study is approved by the Institutional Review Board of Yonsei Cancer Center (4-2023-0920) and is actively recruiting patients towards the completion target of December 2026.
- Results of this proof-of-concept study will inform subsequent large scale interventional studies.

Figure 1. Schematic overview of the EARLY study



Blood sampling (total = 40 cc), (window period of 60 days prior to surgery)

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