Lung Cancer Screening in Women Who Have Never Smoked with a Family History of Lung Cancer : the NIKE Study

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INTRODUCTION

- In East Asia, many lung cancers occur in women who have never smoked, yet this population is largely excluded from smoking-based LDCT screening criteria.
- Prospective Asian studies, particularly TALENT, suggest that family history can identify never-smokers with lung cancer detection rates comparable to conventional high-risk populations. However, the generalizability and clinical benefit of this approach remain uncertain.
- Familial risk is heterogeneous and may vary by the number and relationship of affected relatives, potentially allowing further enrichment of screening candidates.
- Screening value should therefore be assessed beyond cancer detection, balancing potential benefit against harms such as invasive procedures for benign findings and overdiagnosis of indolent cancers.

Objectives

- Primary objective

To determine the lung cancer detection rate at baseline LDCT screening (T0).

- Secondary objectives

To evaluate lung cancer detection at subsequent screening rounds (T1 and T2); characterize the stage, histology, and radiologic phenotype of screen-detected cancers; quantify downstream invasive procedures and benign resections; and assess the potential utility of an adjunct plasma-based assay in post-LDCT management.

METHODS

Study Design and Eligibility Criteria

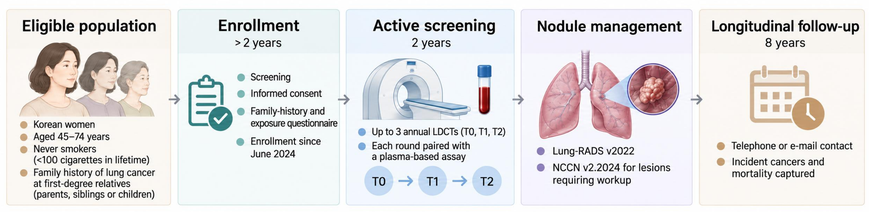
- Prospective, single-arm, single-center screening study at Samsung Medical Center, Seoul. Enrollment commenced in June 2024; this interim analysis includes data available through 31 August 2026.

INCLUSION

Korean women aged 45–74 years
Never smoked (<100 cigarettes in lifetime)
≥ 1 first-degree relative (parent, sibling or child) with lung cancer

EXCLUSION

Prior lung cancer, or any malignancy within 5 years
Unexplained weight loss >5 kg in 12 months, or unexplained hemoptysis
Medical or psychiatric condition precluding participation



RESULTS

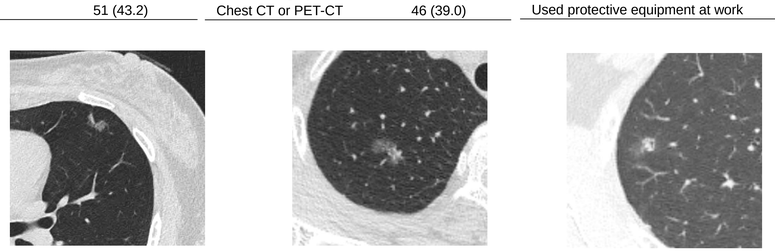
Participants

- Between June 13, 2024 and August 31, 2026, 118 Korean women who had never smoked and had a first-degree family history of lung cancer were enrolled. Mean age was 53.7 ± 6.8 years, and 77% were younger than 60 years.
- Among 106 participants with complete family-history data, 8 (7.5%) had ≥2 affected first-degree relatives and 19 (17.9%) also had an affected second-degree relative.

Characteristics	Participants (n = 118)
Age, years, mean ± SD	53.8 ± 6.8
Body-mass index, kg/m², mean ± SD	22.6 ± 3.5
Highest level of education	
Elementary school	2 (1.7)
Middle school	5 (4.2)
High school	25 (21.2)
Associate degree	15 (12.7)
Bachelor's degree	49 (41.5)
Graduate degree	22 (18.6)
Marital status	
Married	97 (82.2)
Divorced	9 (7.6)
Widowed	5 (4.2)
Never married	7 (5.9)
Current region of residence	
Urban/Metropolis	51 (43.2)

Characteristics	Participants (n = 118)
Medical history	
Hypertension	14 (11.9)
Diabetes mellitus	10 (8.5)
Pulmonary tuberculosis	8 (6.8)
Cardiac disease	3 (2.5)
Asthma	2 (1.7)
Pneumonia	2 (1.7)
Bronchiectasis	1 (0.8)
Chronic bronchitis	1 (0.8)
Prior malignancy	7 (5.9)
Thyroid cancer	4
Breast cancer	2
Renal cancer	1
Previous imaging	
Chest radiograph	115 (97.5)
Chest CT or PET-CT	46 (39.0)

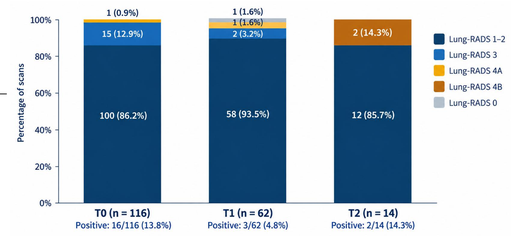
Characteristics	Participants (n = 118)
Environmental tobacco smoke	
Any reported exposure	58 (49.2)
Smoker in the household	52 (44.1)
Worked in a smoky space	16 (13.6)
Source of exposure	
Husband	31 (26.3)
Father	18 (15.3)
Workplace	15 (12.7)
Sibling	3 (2.5)
Duration, years, median (range)	18 (0–45)
Cigarettes/day, median (range)	6 (0–30)
Occupational exposure	
Hazardous occupation for ≥ 1 year	8 (6.8)
Cooking with oil/Baking	7
Asbestos, cotton processing	1
Used protective equipment at work	1 (12.5)



	Case A	Case B	Case C
Age	48	52	64
Round detected	Baseline LDCT, Lung-RADS 4A	T0 → T1 → T2, Lung-RADS 3 → 2 → 4B	T0 → T1, Lung-RADS 4A → 4B
Nodule	Part-solid, 29 mm (solid 7 mm)	Part-solid, 18 mm (solid 6 mm)	Part-solid 12 mm (solid 7 mm)
Surgery	VATS wedge resection	VATS segmentectomy + MLND	VATS wedge resection
Histology	ADC (acinar 95%, lepidic 5%)	ADC (acinar 60%, lepidic 40%)	ADC (lepidic 60%, acinar 40%)
Size	19 × 9 (invasive 19mm)	18 × 16 × 10 mm (invasive 12mm)	12 × 10 × 10 mm (invasive 6mm)
Lymph nodes	Nx	0 / 4 (N0)	Not sampled (N0)
Stage	pT1b Nx M0 — IA2	pT1b N0 — IA2	pT1a N0 — IA1
Biomarkers	EGFR exon 19 del	EGFR L858R	EGFR L858R

Screening results

- A total of 192 LDCT examinations were performed.
- Positive screen-rate: 13.8% at T0, 4.8% at T1, and 14.3% at T2



Screen-detected lung cancers

- Three participants (2.5%) were diagnosed with screen-detected lung cancer. All were adenocarcinomas, pathologic stage I, and completely resected.

Downstream consequences

- No participant underwent bronchoscopic or percutaneous biopsy. Three surgical resections were performed, all for screen-detected cancers, with no benign resections.

CONCLUSIONS

- Among Korean women who have never smoked with a first-degree family history of lung cancer, 3/118 (2.5%) were diagnosed with lung cancer: all stage I, node-negative adenocarcinomas, completely resected.
- Baseline positivity was 13.8%; most findings reverted to Lung-RADS 2
- No invasive procedures were performed for benign disease; downstream burden was primarily surveillance imaging.
- Detection ≠ benefit: 8-year follow-up is needed to distinguish mortality benefit from overdiagnosis.

ACKNOWLEDGEMENTS

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