

A Multicenter Study in Bronchoscopy Combining Stimulated Raman Histology With Artificial Intelligence for Rapid Lung Cancer Detection - The ON-SITE Study

NCT07045103

Status	RECRUITING
Sponsor	Invenio Imaging Inc.
Enrollment	900 participants

Plain Language Summary

This study is testing a new technology that combines stimulated Raman histology (a special high-speed imaging technique) with artificial intelligence to get rapid, same-day results during a lung bronchoscopy procedure — potentially telling doctors right away if a lung lesion is cancerous, without waiting days for lab results.

****You may be eligible if...****

- You are undergoing a bronchoscopy (a procedure where a camera is passed into the airways) for suspected lung cancer
- You have a lung lesion that needs evaluation
- You are 18 or older and able to provide consent

****You may NOT be eligible if...****

- You cannot safely undergo bronchoscopy
- You have conditions that prevent tissue sampling
- You are pregnant or have other serious medical conditions that make the procedure unsafe

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (4)

- The patient or legal guardian is willing and able to understand, sign and date the Ethics committee approved study specific Informed Consent Form.
- The patient is 22 years of age or older.
- The patient is scheduled for routinely indicated staging of the mediastinum (EBUS-TBNA) and planned peripheral lung biopsy procedure (peripheral TBBx/TBNA) with an intermediate to high pretest probability of lung cancer based on clinician suspicion.
- The patient can tolerate the clinical procedure as indicated.

Exclusion (2)

- Patient is a prisoner.
- The participant, in the judgment of the Investigator, may be inappropriate for the intended study procedures

Locations (7 total)

UC San Diego, San Diego, California, United States
Mayo Clinic Jacksonville, Jacksonville, Florida, United States
Corewell Health, Grand Rapids, Michigan, United States
... and 4 more locations

<https://clinicaltrials.gov/study/NCT07045103>

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