

# Breath-hold during robotic bronchoscopy for lung nodule biopsy

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|----------------------------------------|---------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>28/08/2026   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>01/09/2026 | <b>Overall study status</b><br>Ongoing            | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>01/09/2026       | <b>Condition category</b><br>Respiratory          | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Lung nodules and other unusual areas in the lung sometimes need a biopsy to find out whether they are cancer or another condition. Robotic bronchoscopy is a minimally invasive procedure that uses a robotic system and imaging to guide biopsy tools through the airways to reach these areas.

The aim of this study, called STABLE, is to find out whether briefly holding a patient's breathing during tissue sampling can improve the success of robotic bronchoscopy. Researchers want to know if this approach helps keep the biopsy tool in the correct position and increases the chance of obtaining an accurate diagnosis. The study will also look at how well lung lesions can be located, the amount of radiation used, the number of biopsy samples taken, and any complications that occur.

### Who can participate?

Adults aged 18 years or older who have a peripheral lung lesion that requires a diagnostic biopsy may be able to take part. Participants must already be scheduled to undergo robotic bronchoscopy using advanced imaging techniques and be able to have the procedure under general anaesthesia. They must also be willing and able to provide written informed consent.

### What does the study involve?

This is a randomised study involving 150 participants. Before the procedure, participants are allocated by chance to one of two groups.

One group has sustained breath-hold ventilation during tissue sampling. The other group has conventional ventilation during tissue sampling. Apart from this difference, both groups undergo the same standard robotic bronchoscopy and imaging procedures.

During the procedure, doctors collect tissue samples from the lung lesion for testing.

Researchers then compare how often the procedure provides a clear diagnosis in each group.

Participants may also be followed through their medical records so that researchers can confirm the final diagnosis if needed.

### What are the possible benefits and risks of participating?

Participants may not receive any direct benefit from taking part. However, the information collected could help improve robotic bronchoscopy procedures for future patients with lung

lesions.

The risks are similar to those normally associated with robotic bronchoscopy and lung biopsy procedures. These include pneumothorax (a collapsed lung) that may require a chest tube and bleeding that may require medical treatment. Participants will also be exposed to radiation from the imaging used during the procedure. The study will monitor these events carefully.

Where is the study run from?

Winro Ventures LLC (USA)

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

January 2025 to October 2027

Who is funding the study?

Winro Ventures LLC (USA)

Who is the main contact?

Dr Roshen Mathew, mathew.roshen@gmail.com

## Contact information

### Type(s)

Public, Scientific, Principal investigator

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## Additional identifiers

## Study information

### Scientific Title

Study of Tool-lesion Alignment and Breath-hold ventilation in robotic bronchoscopy for peripheral lung LEsions (STABLE)

### Acronym

STABLE

### Study objectives

**Primary objective:**

To determine whether sustained breath-hold during tissue acquisition improves strict diagnostic yield during imaging-integrated robotic bronchoscopy compared with conventional ventilation

**Hypothesis:**

Sustained breath-hold during tissue acquisition will improve strict diagnostic yield by reducing respiratory movement of the target lesion and improving stability of the lesion-biopsy tool relationship

**Secondary endpoints:**

1. Successful lesion localization using integrated imaging
2. Imaging-confirmed tool-lesion relationship: tool-in-lesion (TIL), tool-touching-lesion (TTL), or no tool in lesion (NTL)
3. Diagnostic yield according to imaging-confirmed tool-lesion position
4. Radiation exposure, including fluoroscopy time, cumulative air kerma, dose-area product, and number of C-arm spins
5. Procedural sampling measures, including number of transbronchial needle aspiration passes and transbronchial forceps biopsy specimens
6. Number of sustained breath-holds performed in the breath-hold group
7. Clinically significant complications, including pneumothorax requiring chest-tube placement and clinically significant bleeding requiring intervention
8. Longitudinal diagnostic accuracy following clinical, imaging, surgical, or other definitive follow-up when available

**Ethics approval required**

Ethics approval not required

**Ethics approval(s)****Primary study design**

Interventional

**Allocation**

Randomized controlled trial

**Masking**

Blinded (masking used)

**Control**

Active

**Assignment**

Sequential

**Purpose**

Diagnostic

**Study type(s)****Health condition(s) or problem(s) studied**

## Peripheral pulmonary lesions requiring diagnostic biopsy

### Interventions

This is a prospective randomized study. After enrollment and before the procedure, patients are individually randomized to sustained breath-hold or conventional ventilation using computer-based simple randomization with equal probability of assignment. Assignment is generated at the time of randomization, with no pre-generated allocation sequence available to the procedural team.

#### Intervention arm:

##### Sustained breath-hold ventilation:

Participants underwent robotic bronchoscopy under general anesthesia with mechanical ventilation. Augmented fluoroscopy and C-arm-based tomosynthesis were used for lesion localization and confirmation of tool position, with brief breath-hold during imaging acquisition as required by the imaging workflow. During tissue acquisition, ventilation was held using a standardized sustained breath-hold strategy while transbronchial needle aspiration and/or transbronchial biopsy specimens were obtained. Breath-hold was repeated as clinically appropriate and could be discontinued at any time if required for patient safety.

#### Control arm:

##### Conventional ventilation:

Participants underwent the same robotic bronchoscopy, anesthesia, imaging, lesion localization, and tissue-sampling procedures. Brief breath-hold was similarly used during augmented fluoroscopy and C-arm-based tomosynthesis imaging acquisition. However, during tissue acquisition, conventional mechanical ventilation was resumed/continued rather than maintaining sustained breath-hold.

#### Duration and follow-up:

The randomized intervention was limited to the robotic bronchoscopy procedure. No additional treatment was administered as part of the study. Participants received routine post-procedure care and were subsequently followed through the medical record and available clinical and imaging follow-up to establish the final diagnosis and assess diagnostic accuracy.

### Intervention Type

Procedure/Surgery

### Primary outcome(s)

1. Diagnostic yield measured using review of pathology, cytology, and microbiology results from the index robotic bronchoscopy, classified as a specific malignant or specific benign diagnosis using predefined diagnostic criteria, at following the index robotic bronchoscopy when final pathology and microbiology results are available

### Key secondary outcome(s)

1. Lesion localization success measured using intraprocedural robotic navigation, augmented fluoroscopy, and C-arm-based tomosynthesis imaging during the index robotic bronchoscopy  
2. Tool-lesion relationship measured using intraprocedural augmented fluoroscopy and C-arm-based tomosynthesis imaging, categorized as tool-in-lesion (TIL), tool-touching-lesion (TTL), or not-touching-lesion (NTL) during the index robotic bronchoscopy before tissue acquisition  
3. Radiation exposure measured using fluoroscopy system-recorded fluoroscopy time, cumulative air kerma (mGy), dose-area product (Gy·cm<sup>2</sup>), and number of C-arm imaging acquisitions during the index robotic bronchoscopy

4. Number of biopsy samples measured using procedural record documenting the number of transbronchial needle aspiration and transbronchial biopsy samples obtained during the index robotic bronchoscopy
5. Sustained breath-hold utilization measured using procedural record documenting the number of sustained breath-hold maneuvers performed during tissue acquisition during the index robotic bronchoscopy
6. Procedure-related complications measured using review of procedural and post-procedure medical records for pneumothorax, bleeding requiring intervention, and other clinically significant procedure-related adverse events during the index robotic bronchoscopy and immediate post-procedure period
7. Longitudinal diagnostic accuracy measured using medical-record review of subsequent pathology, microbiology, clinical assessment, and serial imaging to establish the final diagnosis and compare it with the index bronchoscopic diagnosis, measured from the index robotic bronchoscopy through the predefined clinical follow-up period of 1.5 years

**Completion date**

30/10/2027

## Eligibility

**Key inclusion criteria**

1. Adults aged  $\geq 18$  years
2. Presence of a peripheral pulmonary lesion requiring diagnostic biopsy
3. Scheduled to undergo robotic bronchoscopy with augmented fluoroscopy and C-arm-based tomosynthesis for tissue acquisition
4. Able to undergo the procedure under general anesthesia with mechanical ventilation
5. Able and willing to provide written informed consent as required for robotic bronchoscopy procedure

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 Years

**Upper age limit**

100 Years

**Sex**

All

**Total final enrolment**

150

**Key exclusion criteria**

1. Age  $< 18$  years
2. Inability or unwillingness to provide informed consent

3. Inability to safely undergo general anesthesia or mechanical ventilation
4. Clinical or anesthetic circumstances in which sustained breath-hold ventilation was considered unsafe or not feasible
5. Inability to undergo the planned robotic bronchoscopy procedure

**Date of first enrolment**

01/01/2025

**Date of final enrolment**

30/06/2026

## Locations

**Countries of recruitment**

United States of America

## Sponsor information

**Organisation**

Winro Ventures LLC

## Funder(s)

**Funder type****Funder Name**

Winro Ventures LLC

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available

**Study outputs**

| Output type                   | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol file</a> |         |              | 28/08/2026 | No             | No              |