Feasibility and Safety of Remote Robotic Bronchoscopy System in Diagnosis of Peripheral Pulmonary Lesions: a Multicenter, Randomized Controlled, Proof-of Concept Trial

NCT06613412

Status	RECRUITING
Phase	Not Applicable
Sponsor	Guangzhou Medical University
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (3)

• Patients are eligible for inclusion if they meet all of the following criteria:

• Age e18 years and d75 years, with no gender restrictions; Presence of a peripheral lung lesion on chest CT \[Peripheral lung is defined as a nodule located in the fourth-order or higher airway (with the carina defined as order 0, the left and right main bronchi defined as order 1, lobar bronchi as order 2, segmental bronchi as order 3, and subsegmental bronchi as order 4)\] in patients who require biopsy \[2. The population requiring biopsy refers to individuals identified with an occupational lung lesion/nodule (including solid nodules, part-solid nodules, and ground-glass nodules) during clinical trial screening or with risk factors, and who, after comprehensive assessment by a clinician of the patient's clinical information, imaging, tumor markers, and functional imaging, are highly suspected of having cancerous nodules. Bronchoscopy biopsy is planned to further clarify the diagnosis and to guide staging treatment based on pathological results.\]; Patients voluntarily agree to undergo bronchoscopy and meet the requirements for the procedure; Patients are capable of understanding the purpose of the trial, demonstrate good compliance with the examinations and follow-up, voluntarily participate in the clinical trial, and sign an informed consent form.

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Exclusion (3)

• Patients who meet any of the following criteria will be excluded from this study:

• Presence of contraindications for bronchoscopy, including: active massive hemoptysis; recent myocardial infarction or unstable angina; severe cardiac or pulmonary dysfunction; severe hypertension and arrhythmias; uncorrectable bleeding tendencies or severe coagulation disorders (such as platelet count \<60×10\^9/L), uremia; severe pulmonary artery hypertension; severe superior vena cava syndrome; intracranial hypertension; acute cerebrovascular events; aortic dissection or aneurysm; multiple bullae; extreme systemic exhaustion; 2.Female patients who are breastfeeding, pregnant, or planning pregnancy; 3.Patients with electromagnetic active implantable medical devices; 4.Subjects allergic to anesthetics; or with a history of multiple severe allergies, hereditary allergy history; 5.Those who have participated in or are currently participating in drug clinical trials within 3 months before screening, or have participated in other medical device clinical trials within 30 days; 6.Any other conditions deemed unsuitable for participation in this clinical trial by the investigator.

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Locations (1 total)

The First Affiliated Hospital of Guangzhou Medical University, Guangzhou, Guangdong, China