Informed Consent Form

Red Dichromatic Imaging for Improving Post-Biopsy Bronchoscopic Field Visibility

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Dear participant,

You are invited to take part in a clinical study entitled “Red Dichromatic Imaging for Improving Post-Biopsy Bronchoscopic Field Visibility” Before deciding whether to participate, please read the following information carefully. It is intended to help you understand the study, why it is being conducted, what procedures and time commitment are involved, and the possible benefits, risks, and inconveniences of participation.

1.Study background

Bronchoscopic biopsy is an important method for obtaining tissue from abnormal lesions inside the airway. It is commonly used for endobronchial neoplasms, mucosal abnormalities, airway stenosis, and other airway lesions of unclear cause. Whether the lesion is a malignant tumor, inflammatory lesion, granulation tissue, or another benign lesion, local bleeding and blood coverage after biopsy may affect visualization of the procedural field. Most bleeding is mild; however, immediately after biopsy, local blood coverage may make it harder to distinguish the biopsy wound, the lesion surface, and the surrounding mucosa, which may affect localization for subsequent tissue sampling and procedural continuity.

Current management of bleeding after bronchoscopic biopsy mainly includes local vasoactive medication and, when necessary, balloon compression. These methods can usually control obvious active bleeding, but they may have limited ability to improve the clarity of the procedural field. When additional tissue sampling or further treatment is still needed, residual blood, attached clots, or continuous oozing can make it difficult to keep the field clear.

Red dichromatic imaging (RDI) is an optical image-enhancement technology introduced by Olympus. It uses multispectral light of relatively longer wavelengths, mainly green light at 520–550 nm, amber light at 595–610 nm, and red light at 620–640 nm. Through differences in the absorption and scattering of light by hemoglobin, RDI enhances brightness and color contrast, thereby improving visual distinction between areas with different degrees of bleeding.

RDI has already been used in gastrointestinal endoscopy, especially for visualization during bleeding and hemostasis. Studies have shown that RDI can improve field clarity after bleeding during endoscopic procedures and help operators identify bleeding sources and blood vessel courses more quickly, thereby improving procedural safety.

However, systematic use and research on RDI in respiratory endoscopy remain limited. This study therefore focuses on the immediate procedural field after the first bronchoscopic biopsy and before any field-clearing or hemostatic intervention. The study uses a multicenter, prospective, within-subject paired design to compare RDI with white-light imaging (WLI) in terms of the proportion of procedural fields judged suitable for direct continuation of subsequent biopsy or operation. The study will also compare objective color difference and subjective visual discriminability between the bleeding area and the surrounding blood-covered area under the two imaging modes, and will explore the potential value of RDI for subsequent sampling localization, procedural continuity, and safety.

2.Study purpose

The purpose of this study is to evaluate whether RDI, compared with WLI, can improve visualization of the procedural field after the first bronchoscopic biopsy and increase the proportion of cases in which subsequent biopsy or operation can be continued directly. The study will also assess the potential value of RDI for subsequent sampling localization and procedural continuity by combining subjective visibility scores, objective color differences, and safety indicators.

3. Study Procedures

This study will include patients with visible abnormal endobronchial lesions under bronchoscopy that require biopsy to determine their nature. All participants will meet the routine clinical indications for bronchoscopy and biopsy. The procedures will follow relevant domestic and international guidelines, including the Chinese Technical Specification for Diagnostic Bronchoscopy (2021 edition) and the British Thoracic Society guideline for diagnostic flexible bronchoscopy in adults.

Patients who agree to undergo bronchoscopic biopsy and participate in this study will sign an informed consent form. Patient information will be collected for study analysis.

(1). Study type: This is a multicenter, prospective, within-subject paired clinical study.

(2). Study period and follow-up period: July 2026 to December 2026.

(3). Planned enrollment: Based on previous studies and sample-size calculation, approximately 206 participants will be enrolled in total. The First Affiliated Hospital of Ningbo University is expected to enroll 36 participants.

Inclusion criteria

a. Age ≥18 years.

b. Visible abnormal endobronchial lesion under bronchoscopy, including endobronchial neoplasm, mucosal abnormality, airway stenosis, or other lesion requiring biopsy to determine its nature.

c. Voluntary agreement to participate in this clinical study and signing of the informed consent form.

Exclusion criteria

a. Presence of contraindications to bronchoscopy, such as severe cardiopulmonary disease, coagulation dysfunction (including patients receiving anticoagulant therapy and/or anticoagulant drugs who have not discontinued these drugs for more than 5 days before the examination), poor tolerance of anesthesia, psychiatric disease, or severe neurosis.

b. Intra-procedural decrease in SpO_2 or inability to tolerate bronchoscopy.

c. Obvious airway bleeding observed during bronchoscopy that may increase the risk of worsening the patient’s condition.

d. Images that are obviously blurred or out of focus, or that contain severe reflection, bubbles, or instrument obstruction, making subsequent image analysis impossible.

e. Inability to cooperate with the study for any reason, or any other condition that the investigator considers unsuitable for study participation.

Criteria for study discontinuation

a. You may stop participating in the study at any time without prejudice. If you stop participating, the reason will be recorded in the electronic case report form (eCRF).

b. The sponsor or regulatory authority terminates the study.

4. What Do You Need to Do If You Participate

Please provide truthful information about your medical history and current physical condition. Please promptly tell the investigator about any discomfort that occurs during the study so that the investigator can assess it and provide appropriate medical treatment or advice to protect your safety. Please do not take restricted medications or foods as instructed. Please tell the investigator whether you have recently participated in another study or are currently participating in another study, and whether you are pregnant, breastfeeding, or in any other special condition. Please also inform the investigator of any other matter that may be related to or affect this study.

Before you are enrolled, the doctor will ask about and record your medical history and perform a physical examination. You will undergo tests such as complete blood count, liver function, renal function, electrolytes, coagulation function, blood gas analysis, hepatitis B serology, syphilis and HIV antibody testing, electrocardiography, and chest CT, as clinically indicated, to determine whether you can participate in the study. If you meet the eligibility criteria, you may voluntarily participate and sign the informed consent form. If you do not wish to participate, your doctors will still treat you according to your wishes and clinical needs.

The purpose, risks, and possible complications of the procedure will be explained to you in detail, and you will sign an informed consent form. The general procedure will also be explained before the examination to help reduce anxiety, stabilize blood pressure and heart rate, and facilitate cooperation. You will fast from food and water for 4 hours before the procedure. An intravenous line will be established, and fluids may be supplemented as needed until the examination is completed.

If you voluntarily participate, tissue samples from the abnormal mucosal lesion will be obtained for pathology as part of clinically indicated bronchoscopic biopsy. Your diagnosis and treatment will be performed according to the Chinese Technical Specification for Diagnostic Bronchoscopy (2021 edition) and the British Thoracic Society guideline for diagnostic flexible bronchoscopy in adults.

5. Possible Benefits of Participation

This is an observational study. Participation in this study will not necessarily improve your condition, and direct benefit to you cannot be guaranteed. Your routine clinical diagnosis and treatment plan will not be changed because of participation. Your doctor will continue to perform examinations and treatment according to your specific condition and clinical standards. However, the information obtained from this study may help future patients with the same or similar conditions and contribute to medical knowledge. We thank you for your contribution.

6. Common intra-procedural and postoperative adverse reactions and risks of bronchoscopy

(1). Bronchospasm or asthma attack.

(2). Airway mucosal injury and bleeding.

(3). Arrhythmia.

(4). Postoperative chills or fever.

(5). Pneumothorax and bleeding.

(6). Allergy to anesthetic drugs.

(7). Failure to achieve the diagnostic purpose, such as a biopsy pathology report inconsistent with the clinically suspected condition.

7. Risk prevention

(1). Routine examinations should be performed before the procedure and contraindications carefully excluded.

(2). The procedure should be standardized and performed gently.

(3). If adverse reactions or complications occur, the study physician will provide appropriate management according to the specific situation.

8. Costs

All examinations required in this study are performed according to clinical needs. There will be no additional examination or treatment fees specifically due to the study. When undergoing bronchoscopic biopsy, the anesthesia method may be local or general anesthesia. General anesthesia costs 810 RMB for endotracheal intubation general anesthesia, and the material fee is 72 RMB for the laryngeal mask airway/tracheal tube. There is no anesthesia fee for local anesthesia.

Compensation for study participation: There is no study-related compensation fee in this study.

9. Compensation for Research-Related Injury

If you experience any discomfort or unexpected situation during the study, regardless of whether it is related to the study, you should promptly inform the study doctor. The doctor

will assess the situation and provide medical management. If your injury is confirmed to have been caused by the study, the sponsor will bear reasonable treatment costs and provide corresponding economic compensation or reimbursement in accordance with the relevant laws of the People's Republic of China.

10. Alternative Treatment and Its Main Benefits and Risks

This is a multicenter, prospective, paired clinical study. If you do not wish to participate, your clinical treatment will not be affected. You may choose an alternative approach according to your wishes and clinical needs. The alternative is to undergo biopsy and post-biopsy management under WLI only, without switching to RDI mode.

11. Confidentiality of Your Personal Information

Your medical records, including study medical records, case report forms, laboratory reports, and other relevant documents, will be kept completely at the hospital where you receive care. The doctor will record test results in your medical records. Without violating confidentiality principles and relevant regulations, investigators, monitors, auditors, the ethics committee, and regulatory authorities may be allowed to review your medical records. Any public report of the results of this study will not disclose your identity. We will make every effort, to the extent permitted by law, to protect the privacy of your personal medical information.

Data and personal information of study participants involved in this study will be used only for this study. They will not be provided externally and will not be used for product development, sharing, or secondary use.

Study results will not be directly fed back to individual participants. The results may be published in medical journals, but your identity will not be disclosed, and all information that can identify you will be kept confidential.

12. Voluntary Participation and Withdrawal

Participation in this study is entirely voluntary. You may refuse to participate or withdraw from the study at any time. This will not affect your relationship with your doctors, will not affect your medical care, and will not cause you any other loss.

For your best interests, your doctor, the investigator, or the ethics committee may terminate your continued participation in this study at any stage.

Notification of new information: If new important information becomes available after you participate that may affect your decision to continue in the study, we will promptly inform you. You may then reconsider whether to continue participation or withdraw from the study.

13. Who to Contact If You Have Questions

If a research-related injury occurs, or if you have any questions about this study, please contact the study doctor: Zhongbo Chen; telephone: 13777125910. This study has been reviewed and approved by the Medical Ethics Committee of The First Affiliated Hospital of Ningbo University. For questions about ethics and participant rights, you may contact the

Office of the Medical Ethics Committee of The First Affiliated Hospital of Ningbo University at 0574-87085233.

14. What Should You Do Now?

Whether to participate in this study is your own decision, or the decision of you and your legal representative when applicable. Before deciding to participate, please ask your doctor any questions you may have. Thank you for reading this document. If you decide to participate, please tell your doctor, and he/she will arrange all study-related matters for you. Please keep a copy of this document.

15. Consent Statement and Signatures

I confirm that I have read and understood this informed consent form. I have had the opportunity to ask questions, and all of my questions have been answered. I understand that participation in this study is voluntary and that choosing not to participate or withdrawing at any time will not affect or harm my rights and interests. I voluntarily agree to participate in this study, including the study procedures described above, and agree that my medical data may be used for publication related to this study.

Participant signature: _____ Contact information: _____

Date: _____ year _____ month _____ day Time: _____ : _____

Legal representative signature (if needed): _____
Relationship to participant: _____

Contact information: _____ Date: _____ year _____ month _____ day Time: _____ : _____

Statement of impartial witness when the participant or legal representative is unable to read: I confirm that the information in this informed consent form has been explained to the participant and/or his/her legal representative, that the participant and/or legal representative has understood the information, and that he/she voluntarily agrees to participate in this study.

Impartial witness (if needed): _____ Contact information: _____

Date: _____ year _____ month _____ day Time: _____ : _____

I confirm that I have explained the details of this study to the participant, including his/her rights and possible benefits and risks.

Investigator signature: _____ Date: _____ year _____ month _____ day Time: _____ : _____

Contact information (mobile phone): _____