# Cover Page

**Clinical Study (No. HZ（2019）146)**

**Study on Bronchoscopy for the Treatment of Post-Stroke Dysphagia and Stroke-Associated Pneumonia**

**Study Type:** Interventional Study

**Study Center:** Zunyi First People's Hospital

**Date:** September 01, 2019

**Informed Consent Form · Information Sheet**

**Subject:**

You have been diagnosed by a physician with Stroke-Associated Pneumonia. We are inviting you to participate in a study titled Study on Bronchoscopy for Treating Post-Stroke Dysphagia and Stroke-Associated Pneumonia. This study is part of the Zunyi City Science and Technology Plan project, with project number: Zun Shi Ke He HZ Zi (2019) No. 146. This study protocol has been reviewed and approved by the Ethics Committee of Zunyi First People's Hospital for clinical research.

Before you decide whether to participate in this study, please read the following content as carefully as possible. It can help you understand the study and why it is being conducted, the study procedures and duration, and the potential benefits, risks, and discomforts associated with participation. If you wish, you can also discuss this with your relatives or friends, or ask the physician for explanation to help you make your decision.

**1. Research Background and Purpose**

**1. Disease Burden and Current Treatment Status**

Stroke is the third leading cause of disability and the second leading cause of death globally. Stroke-Associated Pneumonia (SAP) is one of the most common respiratory complications of acute stroke. SAP usually occurs due to

stroke-associated dysphagia (i.e., impaired motor and sensory mechanisms of swallowing) or decreased level of consciousness leading to impaired cough reflex and glottic closure. Bedside bronchoscopy can clear airway secretions, promote cough and swallowing movements, play a positive role in preventing aspiration and alleviating dysphagia, and directly stimulate the trigeminal nerve of the soft palate, the glossopharyngeal nerve of the posterior pharyngeal wall, and the vagus nerve of the epiglottis. This promotes contraction of the masticatory muscles, suprahyoid muscles, infrahyoid muscles, facial muscles, tongue muscles, and soft palate muscles, thereby training the swallowing muscle groups, exercising swallowing function, improving swallowing disorders, and significantly reducing the incidence and mortality rate of SAP.

**2. Purpose of This Study**

To explore new treatment methods for post-stroke dysphagia and Stroke-Associated Pneumonia.

**3. Participating Research Unit and Expected Number of Participants**

Sixty non-severe ischemic SAP patients with dysphagia from our hospital's intensive care unit will be selected and randomly divided equally into a treatment group and a control group. The control group will receive conventional anti-infective drugs, expectorants, and sputum suction via suction catheter. The treatment group will receive sputum suction and

bronchoalveolar lavage via fiberoptic bronchoscope, with drug treatment the same as the control group. The two groups will be compared regarding heart rate, respiration, blood pressure, blood oxygen saturation, arterial blood gas analysis, procalcitonin, interleukin-32, lung function, C-reactive protein, Clinical Pulmonary Infection Score (CPIS), dysphagia assessment scales, and adverse reactions.

**II. Who Should Not Participate in the Study**

Based on the population defined by different research purposes and study drugs.

Additionally, 1) Patients currently participating in other clinical trials; 2) Patients deemed by the researchers to be unsuitable for the clinical trial for other reasons.

**III. What Will Be Required If You Participate in the Study?**

1. Before you are enrolled in the study, the physician will ask about and record your medical history, and perform Blood tests and clinical data collection.If you are an eligible candidate, you can voluntarily participate in the study and sign this informed consent form.If you are unwilling to participate in the study, we will provide treatment according to your wishes.

2. If you voluntarily participate in the study, the following steps will be taken:After enrollment, you will be randomly assigned to one of two groups. The control group will receive conventional anti-infective drugs, expectorants, and sputum suction via suction catheter. The treatment group will receive sputum suction and bronchoalveolar lavage via fiberoptic bronchoscope, with drug treatment the same as the control group. The two groups will be compared regarding heart rate, respiration, blood pressure, blood oxygen saturation, arterial blood gas analysis, procalcitonin, interleukin-32, lung function, C-reactive protein, Clinical Pulmonary Infection Score (CPIS), dysphagia assessment scales, and adverse reactions.
3. Other matters requiring your cooperation

   You must come to the hospital for appointments at the times agreed upon with your physician, bringing (ID card, medical card, medical record, etc.) (During the follow-up phase, the physician may contact you via phone or visit to understand your condition). Your follow-up is very important because the physician will determine whether the treatment you are receiving is truly effective and provide you with timely guidance.

   You must take medication as instructed by the physician, and please fill out your medication record promptly and objectively. At each follow-up visit, you must return any unused medication and its packaging, and

bring any other medications you are taking, including those you must continue taking for other comorbid conditions.

**IV. Potential Benefits of Participating in the Study**

State the potential benefits for the patient.

Although evidence already suggests that bronchoscopy treatment for Stroke-Associated Pneumonia has satisfactory efficacy, this does not guarantee that it will definitely be effective for you. The intervention measures used in this study are also not the only method for treating Stroke-Associated Pneumonia. If the intervention measures are ineffective for your condition, you can ask your physician about possible alternative treatment methods.

**V. Potential Adverse Reactions, Risks, Discomforts, and Inconveniences of Participating in the Study**

Inform about the potential adverse reactions, risks, discomforts, and inconveniences of participating in the study, and clearly state the handling plan and possible compensation plan.

If you experience any discomfort during the study period, or if your condition changes in new ways, or any unexpected circumstances arise, whether related to the study or not, you should promptly notify your physician, who will make a judgment and provide appropriate medical treatment.

During the study period, you will need to come to the hospital for follow-up visits on time and undergo some tests. This will take up some of your time and may cause you trouble or inconvenience.

**VI. Related Costs**

The treatment and examinations required for other diseases you may have simultaneously will not be covered free of charge.

**VII. Confidentiality of Personal Information**

Your medical records (study medical records/imaging data, lab reports, etc.) will be kept intact at the hospital where you are receiving treatment. The physician will record laboratory and other test results in your medical record. The investigators, Ethics Committee, and drug regulatory authorities will be permitted to access your medical records. Any public reports regarding the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical data within the limits permitted by law.

In accordance with medical research ethics, except for personal privacy information, the trial data will be available for public query and sharing. Query and sharing will be limited to web-based electronic databases, ensuring that no personal privacy information is leaked.

**VIII. How to Obtain More Information?**

You can ask any questions about this study at any time and will receive corresponding answers.

If any significant new information arises during the research process that might affect your willingness to continue participating in the study, your physician will notify you promptly.

**IX. Voluntary Participation and Withdrawal from the Study**

Whether you participate in the study depends entirely on your willingness. You can refuse to participate in this study, or withdraw from this study at any time during the research process. This will not affect the relationship between you and your physician, nor will it affect your medical care or result in any other loss of benefits.

Considering your best interests, the physician or investigator may discontinue your participation in this study at any time during the research process.

If you withdraw from the study for any reason, you may be asked about your use of the investigational drug. If the physician deems it necessary, you may also be required to undergo laboratory tests and physical examinations.

**X. What to Do Now?**

The decision to participate in this study is up to you (and your family).

Before you make the decision to participate in the study, please ask your physician as many questions as needed.

Thank you for reading the above materials. If you decide to participate in this study, please inform your physician, and he/she will arrange all matters related to the study for you. Please keep this document.

**Informed Consent Form · Consent Signature Page**

**Clinical Research Project Name:** Study on Bronchoscopy for Treating Post-Stroke Dysphagia and Stroke-Associated Pneumonia

**Project Undertaking Unit:** Zunyi First People's Hospital

**Project Collaborating Unit(s):** None.

**Project Task Document Number:** Zun Shi Ke He HZ Zi (2019) No. 146

**Statement of Consent**

I have read the above introduction regarding this study and have had the opportunity to discuss this study with the physician and ask questions. All the questions I have raised have been answered satisfactorily.

I understand the potential risks and benefits that may arise from participating in this study. I know that participation in the study is voluntary, I confirm that I have had sufficient time to consider this, and I understand that:

- I can consult the physician for more information at any time.
- I can withdraw from this study at any time without discrimination or retaliation, and my medical treatment and rights will not be affected.

I am also aware that if I withdraw from the study midway, especially due to reasons related to the drug, it would be very beneficial for the overall study if I

inform the physician of any changes in my condition and complete the corresponding physical examination and laboratory tests.

If I need to take any other medications due to changes in my condition, I will seek the physician's opinion in advance or truthfully inform the physician afterwards.

I agree that the drug regulatory authorities, the Ethics Committee, or the sponsor's representative may inspect my research data.

I will receive a copy of this informed consent form, signed and dated.

Finally, I decide to agree to participate in this study and promise to follow the doctor's instructions as much as possible.

**Patient Signature:** _____ Year __ Month __ Day

**Contact Telephone Number:** _____

I confirm that I have explained the details of this trial to the patient, including their rights and the potential benefits and risks, and have provided them with a copy of the signed informed consent form.

**Physician Signature:** _____ Year __ Month __ Day

**Physician's Work Telephone Number:** _____