Informed Consent Form - Information and Disclosure Page

Title	**A Randomized Controlled Study to Explore the Clinical Effect of Intermittent Oro-esophageal Tube Feeding vs. Nasogastric Tube Feeding on Cerebral Small Vessel Disease Patients with Dysphagia**
Applicant	**Zeng Xi**
Version	**V1.0**
Date	**2022.12.10**
Unit	*The First Affiliated Hospital of Zhengzhou University*
Address	Zhengzhou, China
PI	**Zeng Xi**
TEL	**15333828388**
Patient name	
screening number	

Subject Notice

You will be invited to participate in a clinical study initiated by the First Affiliated Hospital of Zhengzhou University, led by Director Zeng Xi, to investigate the clinical effects of intermittent nasogastric tube feeding on swallowing disorders. The study will last for 15 days. This project is funded by the Special Fund for Basic Scientific Research Business Fees of the Central Public Welfare Research Institute of the Chinese Academy of Medical Sciences (2020-PT310-01). It has been approved by the Ethics Committee of the First Affiliated Hospital of Zhengzhou University to conduct the clinical research.

This informed consent form provides you with relevant information about this clinical study to help you decide whether to participate. If you agree to participate in this study, please refer to the following instructions...

Please read carefully, and if you have any questions, please contact the researchers responsible for this study.

2、Background：

Nasogastric tube feeding (NGT) has been widely used in cerebral small vessel disease (CSVD) patients with dysphagia but has a significant risk of complications. Intermittent

Oro-esophageal Tube Feeding (IOE) is an established enteral nutrition approach that can be used with comprehensive rehabilitation therapy. This study aims to explore the clinical effect of IOE vs. NGT on CSVD Patients with Dysphagia.

3、Design：

During the treatment, all patients were provided with comprehensive rehabilitation therapy as follows:

1) Basic treatment, including corresponding control of risk factors and education on healthy lifestyles.
2) Swallowing training, including lemon ice stimulation, Mendelsohn maneuver, empty swallowing training, and pronunciation training.
3) Pulmonary function training, including standing training, cough training, and diaphragm muscle training.

Besides, the control group was given enteral nutritional support with NGT according to the relevant guidelines. Within 4 hours after admission, the placement of the feeding tube was conducted by professional medical staffs and after intubation, the tube was secured to the patient's cheek with medical tape. The feeding was conducted once every 3-4 hours, with 200-300ml each time. The total feeding volume was determined based on daily requirements[18].

The observation group was given enteral nutritional support with IOE according to the following procedure[19]: Before each feeding, inside and outside of the tube was cleaned with water. During feeding, the patient should maintain a semi-reclining or sitting position with mouth opened, and the tube was inserted slowly and smoothly into the upper part of the esophagus by medical staffs while the appropriate depth of intubation was checked with the calibration markings on the tube wall. The distance from the incisors to the head part of the tube should be between 22-25 cm (Appendix). However, the specific depth should be evaluated based on patients' feedback and adjusted accordingly. After insertion, the tail part of the tube should be put into a container full of water and the absence of continuous bubbles indicated a successful intubation. Then, the feeding was to be conducted three times per day with 50 ml per minute and 400-600ml for each feeding. After each feeding, the nutrition tube was removed and placed in a container filled with 20% solution of vinegar for rinsing and storage. For patients with sensitive pharyngeal reflex, a small amount of 2% Lidocaine can be applied to the pharyngeal area for surface anesthesia before tube insertion.

4、Potential Benefit：

Testing your samples will help in assessing the prognosis of the disease, providing necessary recommendations for your treatment, and offering valuable information for the research of the disease. It will also be beneficial for the promotion of this therapy.

5、Risk：

The collection of your samples will be conducted with strict aseptic procedures. There may be minimal risks associated with the sample collection, including transient pain, local bruising, mild dizziness in some individuals, or extremely rare needle site infections.

6、Alternative：

N/A

7、Privacy:

If you decide to participate in this study, your participation and personal information during the study will be kept confidential. All information related to you will be treated as confidential. Any information that could identify you will not be disclosed to anyone outside the research team without your permission. After the research is completed and the data is analyzed, it will be destroyed. During the retention period, you may contact us at any time regarding the use of your data. All research team members and sponsors are required to maintain the confidentiality of your identity. Your files will be kept in a filing cabinet and will only be accessible to the researchers. To ensure compliance with regulations, government regulatory agencies or members of the ethics review committee may, when necessary, inspect your personal information at the research site according to regulations.

When the results of this study are published, a commitment to confidentiality will also be required.

8、Payment and refund:

During your participation in the research, if any research-related injury occurs, you will be entitled to receive free treatment and/or appropriate compensation. The treatment expenses will be provided by the Rehabilitation Department of the First Affiliated Hospital of Zhengzhou University.

9、Free to withdraw:

As a participant, you have the right to access information and updates related to the research at any time and make a voluntary decision to continue or discontinue your participation. After joining the study, regardless of whether an injury occurs or its severity, you have the option to notify the researchers and request to withdraw from the study at any time. Any data collected after your withdrawal will not be included in the research results, and your medical treatment and rights will not be affected as a result.

If you have any questions regarding the research content, please contact the research doctor at 15333828388. If you have any concerns related to your rights, you can contact the Ethics Committee through the contact information provided in the footer of the informed consent form.

10、Achievement sharing:

When the study is completed and the research product or intervention measures have been proven safe and effective, you may continue to use them at normal market prices.

Informed Consent Form for the First Affiliated Hospital of Zhengzhou University - Consent Signature Page

I have carefully read the Informed Consent Form for the clinical trial, and I had the opportunity to ask questions, all of which have been answered. I understand that participation in this trial is voluntary, and I have the choice to decline participation or withdraw at any time without discrimination or retaliation. My medical treatment and rights will not be affected as a result. If I require additional diagnosis/treatment, fail to comply with the trial protocol, or for any other reasonable reason, the researcher may terminate my continued participation in this clinical trial. I willingly consent to participate in this clinical trial, and I will receive a signed copy of the "Informed Consent Form".

Please state: "I have read and understood the clinical trial and voluntarily agree to participate in it." ____

Subject Name (in regular script): _____

Subject signature: _____

Subject's ID number: _____

Contact phone number: _____

Date: _____

（When the subject lacks or has insufficient capacity to give informed consent：）

Guardian's name (in regular script): _____

Signature of guardian: _____

Guardian ID number No.: _____

Relationship with subjects: _____

Contact phone number: _____

Date: _____

（When the subject or their guardian lacks reading ability：）

Name of impartial witness (in regular _____

Signature of impartial witness: _____

Impartial witness ID number: _____

Contact phone number: _____

Date: _____

I have accurately informed the subject of the content of the informed consent form and answered their questions. The subject voluntarily agrees to participate in this clinical trial. A signed copy of the informed consent form has been provided to them.

Research doctor's name _____

Signature of research doctor: _____

Contact phone number: _____

Date: _____