Informed Consent Form - Information and Disclosure Page

Title	**Stellate Ganglion Block: A Breakthrough Treatment for Post-Stroke Pharyngeal Dysphagia**
Applicant	**Zeng Xi**
Version	**V1.0**
Date	**2021.12.10**
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:

Dysphagia is a frequent and potentially serious complication of stroke. However, there is no effective measure for the treatment of pharyngeal dysphagia in stroke patients.

3、Design:

All the participants were provided with the comprehensive rehabilitation (routine rehabilitation and swallowing function training). The routine rehabilitation included intervention for risk factors (blood pressure, blood lipids, blood glucose, smoking and alcohol restriction, exercise, etc.) and pharmacological treatment (aspirin, statins, anticoagulants, etc.).

Regrading swallowing function training, both groups were given swallowing function training, including 1) exercises of closure of the vocal folds, pharyngeal, and laryngeal muscles exercises, and respiratory muscle strength training, for 15 min each time and twice per day. 2) isotonic / isometric swallowing exercises, supraglottic swallowing exercises, and the Mendelsohn maneuver, for 20 min each time and twice per day. 3) effortful swallowing exercises, and cough reflex training, for 10 min each time and twice per day.

Based on these, the observation group was given SGB once a day, with 10 sessions as a course of treatment and each side of the body for one course. All the materials included: 1) 1.5ml of 2% Lidocaine hydrochloride injection (1ml: 0.5mg), Vitamin B12 Injection 500ug (1ml: 0.5g), the 5 ml disposable syringe and the sterile disposable dental injection needles. The specific operation procedure was as follows[16]: The operator stood at the patient's block side, and the patient was placed in the supine position, with the head leaning 45 degrees toward the contralateral side of the block side. After routine disinfection of the skin, a paratracheal approach was adopted, which was, 2.5cm above the sternoclavicular joint and 1.5cm outside the midline of the neck. The operator, with the tips of the index finger and middle finger, pushed the trachea and esophagus to the medial side, and the sternocleidomastoid muscle and common carotid artery to the lateral side. Next, the operator inserted the needle vertically until the needle tip reached the C7 transverse process and then withdrew the needle slightly. If there was no blood or cerebrospinal fluid back drawn, the blocking drug should be slowly injected, and the presence of Horner's syndrome indicated a successful block. After the injection, the patient was required to keep lying down for 30 minutes to ensure there were no abnormal symptoms.

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:	_____