Patient Informed Consent

Study Title:	Antithrombotic Therapy with Regulation of Blood Pressure in Non-Cardioembolic Progressive Stroke
Protocol Number:	2024213
Principal Investigator:	Longxuan Li
Department :	Neurology
Study Period :	August 1, 2024 - July 31, 2025

Ruijin Hospital Affiliated to Shanghai Jiao Tong University School of Medicine

August 5, 2024

Version Number: 1.2

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You will be invited to participate in a clinical study. This informed consent form provides you with some information to help you decide whether to participate in this clinical study. Please read it carefully and ask the researcher in charge of the study if you have any questions .

What is the background and purpose of the study?

Stroke has become the leading cause of death in China, with acute ischemic stroke still progressing within one week of onset, known as progressive ischemic stroke (PIS), which has a high rate of disability and mortality, accounting for 23-43% of the incidence of stroke. Non-cardioembolic PIS is one of the common types, and the current treatment mainly focuses on antithrombotic therapy, but the therapeutic effect is not satisfactory. More and more evidence suggests that hypotension is an unfavorable factor for PIS, so this study intends to explore the efficacy and safety of antithrombotic therapy with regulation of blood pressure in non-cardioembolic PIS and to improve the treatment and management of non-cardioembolic PIS, to improve the quality of life of patients, to reduce the medical burden of patients and their families, and to promote related research and development to solve major issues closely related to people's health, such as standardized diagnosis and treatment and individualized treatment related to stroke.

If I participate in the research, what do I need to do?

This study intends to include 70 subjects with PIS and randomly divide them into two groups:

intervention group (antithrombotic therapy + blood pressure control therapy) and control group (antithrombotic therapy). Study participants (subjects) are required to provide a detailed medical history (especially the current medical history, past history, and personal history that are closely related to the current onset). Subjects are required to cooperate in completing physical examinations , blood tests (blood routine, electrolytes, liver and kidney function, blood sugar, blood lipids, coagulation function, myocardial protein) and imaging examinations such as cranial computed tomography (CT) / magnetic resonance imaging (MRI), head and neck CT angiography (CTA) / magnetic resonance angiography (MRA) evaluation (Note: These tests are required for clinical routine, we only collect test reports), and receive the following drug interventions: After stroke progression, all patients receive dual antiplatelet therapy (aspirin 100mg/day combined with clopidogrel 75mg/day) for the first 21 days, except in cases of cerebral hemorrhage. After this period, they continue to take aspirin 100mg/day orally for the long term; In terms of blood pressure control, medications such as dopamine, metaraminol, or midodrine are used to achieve a systolic blood pressure target range of 160-180 mmHg within 1 h of random assignment and to maintain this target for 7 days (or death, should this events occur earlier). Blood pressure measurements were frequently recorded every 15 min in the first hour, hourly between 1 and 6 h, every 6 h between 6 and 24 h, and then twice daily for 7 days (or death, if earlier), and uploaded to the research database.

Are there risks in the research?

The following adverse drug reactions may occur in this study:

1. Increased risk of bleeding: The use of antithrombotic drugs may lead to an increased risk of bleeding, including nasal bleeding, gingival bleeding, skin ecchymosis, etc.; in addition, antithrombotic combined with increased blood pressure has the risk of new cerebral hemorrhage .

2. Allergic reaction: Some patients may experience allergic reaction after using antithrombotic drugs, manifested by symptoms such as rash, itching, and difficulty breathing;

3. Hypertensive encephalopathy.

The researcher will provide symptomatic treatment based on the patient's condition and comply with the patient's wishes, and the study can be terminated at any time.

What are the possible benefits of participating in research?

By participating in this study, you can get timely treatment in the acute stage of stroke, reducing the risk of death and disability; at the same time, you can get the opportunity to evaluate cerebrovascular

and risk factors, and reduce the risk of stroke recurrence as much as possible. It provides more effective treatment for stroke treatment. In addition, since antithrombotic combined with hypertension has the risk of new cerebral hemorrhage , we purchase insurance for the subjects before enrollment.

Is there any cost or compensation for participating in the study?

This study is a routine clinical diagnosis and treatment. When you participate in this study, we only collect the test and examination reports of routine clinical diagnosis and treatment. The expenses incurred by your hospitalization for disease treatment will be borne by yourself, and no additional expenses will be incurred. However, you will not receive any compensation for participating in this study. Your contribution to the medical cause is very meaningful.

What if I am harmed by participating in research?

If any damage occurs related to this clinical research , you can receive free treatment and/or corresponding compensation .

Is my information kept confidential?

If you decide to participate in this study, your participation in the study and your personal information in the study will be kept confidential. Your biological specimens will be identified by the study number instead of your name. Information that can identify you will not be disclosed to members outside the research team unless you allow it. All research members and research sponsors are required to keep your identity confidential. Your files will be kept in a locked filing cabinet and only accessible to researchers. To ensure that the research is conducted in accordance with regulations, if necessary, members of the government management department or the ethics review committee can access your personal information at the research unit as required . When the results of this study are published, no personal information about you will be disclosed.

Do I have to attend?

You can voluntarily choose to participate in or not participate in this study, or notify the researcher at any time to withdraw from the study. Your data will not be included in the research results , and any of your medical treatment and rights will not be affected.

The study physician may terminate your participation in this study if you require additional treatment, if you do not comply with the study protocol, if you develop a study-related injury , or for other reasons where continued participation may increase your risk of harm from participating

in the study .

Who should I contact for more information?

You can keep up to date with the information and research progress related to this study . If there is any new safety information related to this study, we will notify you in a timely manner. If you have any questions related to this study, or if you experience any discomfort or injury during the study , or if you have any questions about the rights of participants in this study, you can contact us through 13671837830 (*mobile phone number*) and Contact Zhang Yi .

This study has been reviewed **by the Human Research Ethics Committee of Ruijin Hospital, Shanghai Jiao Tong University School of Medicine** . If you have any questions or concerns about your rights and health in this study, you can contact the Ethics Committee of this institution at 64370045-675226; Contact person: Ms. Chen.

Informed consent signature page

I have read this Informed Consent Form.

I had the opportunity to ask questions and all of them were answered.

I understand that participation in this research is voluntary.

I can voluntarily choose to participate in or not participate in this study, or withdraw after notifying the researcher at any time without being discriminated against or retaliated against, and any of my medical treatment and rights will not be affected.

The study physician may terminate my participation in this study if I require additional treatment, if I fail to comply with the study protocol, if a study-related injury occurs, or for other reasons where continued participation may increase my risk of harm from participating in the study .

I will receive a signed copy of the Informed Consent Form .

Subject’s Name: _____

Subject’s Signature: _____

Date : _____ / _____ / _____

Name of legal representative: _____

Signature of legal representative: _____

Date : _____ / _____ / _____

Witness’ Name: _____

Witness Signature: _____

Date : _____ / _____ / _____

(*Note: If the subject is illiterate, a witness' signature is required; if the subject is incapable of acting/has limited capacity for acting, a legal representative's signature is required*)

I have accurately informed the subject of this document and asked him/her to read this informed consent form carefully and answer any questions or doubts raised carefully.

Researcher Name: Longxuan Li

Investigator’s Signature: Longxuan Li

Date : August 5 , 2024