Informed Consent Form

Research Official Title:	A Prospective Study on Safety and Efficacy of Stenting for Chronic Middle Cerebral Artery Occlusion With Limb Dysfunction
File date:	February 25, 2021

A Prospective Study on Safety and Efficacy of Stenting for Chronic Middle Cerebral Artery Occlusion With Limb Dysfunction

Subject's Informed Consent Form

Subject Notice

Research Approval Number: **Subject's Name:**
ID Number: **Tel:**
Address:

Dear participants,

You will be invited to participate in a clinical study, and this informed consent form provides you with some information. Before deciding 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 was conducted, the procedure and duration of the study, and the potential benefits, risks, and discomforts that participating in the study may bring to you. If you are willing, you can also discuss with your relatives and friends, or ask a doctor for an explanation to help you make a decision.

1. Research Background and Purpose

The middle cerebral artery (MCA) is one of the main blood vessels that supply most areas of the cerebral cortex. When chronic occlusion occurs in MCA, it seriously affects blood flow to several important areas of the brain, including areas that control speech, sensation, and motor function. Therefore, MCA occlusion is often associated with severe neurological deficits such as hemiplegia, speech impairment, and cognitive impairment. Chronic MCA occlusion is usually caused by intracranial arteriosclerosis, which is a process whereby the arterial wall accumulates fat and calcium, resulting in vascular stenosis. When blood vessels narrow to a certain extent, blood flow is reduced to a level that is insufficient to meet the needs of brain tissue, which can result in ischemic brain injury. Studies have shown that hypertension and diabetes are the main risk factors for intracranial stenosis and chronic MCA occlusion. These conditions increase the risk of MCA occlusion by accelerating the

process of atherosclerosis, increasing the thickness and stiffness of blood vessel walls. Furthermore, smoking represents another significant modifiable risk factor that increases the risk of atherosclerosis by damaging vascular endothelial function and promoting an inflammatory response.

Although there has been sufficient research on acute MCA occlusion, including vascular recanalization protocols during the acute phase, such as thrombolysis and mechanical thrombectomy, there is relatively limited research on chronic MCA occlusion. Due to the long-term and complex nature of the disease course, the treatment strategies and prognosis evaluation for patients in the chronic phase are not yet clear. In addition, for patients who have not received timely or ineffective acute treatment, the challenge of improving their long-term prognosis through interventional treatment is a significant area of current research.

Previous case reports and retrospective studies have shown that even after years of MCA occlusion, vascular reconstruction surgery can still successfully restore blood flow and achieve favourable therapeutic outcomes. Nevertheless, at present, the vascular reconstruction treatment for chronic MCA occlusion is predominantly based on case reports, with a paucity of systematic prospective studies to validate the safety and efficacy of these treatments.

The objective of this study is to evaluate the safety and efficacy of stent placement in patients with chronic MCA occlusion, and to investigate the impact of stent placement on blood flow recovery, reduction of reocclusion rates, and improvement of neurological function recovery.

Given the above background, this study aims to fill this research gap by systematically evaluating the efficacy and safety of stent placement in patients with chronic MCA occlusion through prospective clinical trials. This will provide more scientific and standardized treatment guidance for such patients.

2. Research Introduction

Basic information about this clinical study (including whether the study has been approved by the ethics committee, research overview, main research content, process and duration, examination procedures, etc.).

Review:

(This study will be conducted at the Neurology Department of Huizhou Central People's Hospital, with an estimated 60 participants voluntarily participating. The selection criteria for the participants will include informing them of the different groups they may be assigned to the study.)

(This study has been approved by the Ethics Committee of Huizhou Central People's Hospital. The Ethics Committee of Huizhou Central People's Hospital has reviewed that this study complies with the principles of the Helsinki Declaration and is in line with medical ethics.)

Main research content:

This study adopts a prospective, single center, observational clinical trial design. By setting up a stent group and a control group, the therapeutic effects of the two groups of patients were compared

to evaluate the safety and effectiveness of stent placement in patients with chronic middle cerebral artery (MCA) occlusion. This study has been approved by the Clinical Ethics Committee of Huizhou Central People's Hospital in terms of human research ethics, and strictly adheres to relevant ethical standards and guiding principles.

Process and deadline: March 2021 to January 2024

Examination procedure: Patients in the control group received aspirin treatment, while patients in the stent group underwent stent placement surgery on the basis of aspirin treatment.

3. Who is Not Suitable to Participate in Research

1) Patients who are currently participating in other clinical studies; 2) Patients who are considered by the researchers to be unsuitable for clinical studies for other reasons.

4. What Will be Required to Participate in The Research?

1) Before you are selected for the study, the doctor will inquire and record your medical history, and perform magnetic resonance imaging (MRI) or computed tomography (CT) examination.

   You are a qualified enroll**ee a**nd can voluntarily participate in the study by signing an informed consent form.

   If you are unwilling to participate in this study, we will provide other appropriate treatments according to your condition and wishes.

2) If you voluntarily participate in the study, you will follow the following steps:

   Patients will be randomly assigned to either the stent group or the control group. The control group received aspirin treatment, while the stent group underwent stent placement surgery on the basis of aspirin treatment.

3) Other matters that require your cooperation as a test subject.

   During the follow-up period, you must complete the scale according to the agreed follow-up time between the doctor and you to evaluate symptom relief. Because doctors will determine whether the treatment you receive is truly effective and provide timely guidance to you.

   If you need other treatments, please contact your research doctor in advance.

5. Possible Benefits of Participating in Research

State the potential benefits that the subjects may receive.

Although there is evidence to suggest that stent placement has satisfactory therapeutic effects, this does not guarantee a definite effectiveness for you. The stent placement technique used in this study is not the only method for treating chronic occlusion of the middle cerebral artery (MCA). If stent placement is ineffective for your condition, you can inquire with your doctor about possible

alternative treatment options.

6. Possible Adverse Reactions, Risks, Discomfort, and Inconvenience Associated with Participating in Research

If you experience any discomfort, new changes in your condition, or anyunexpected circumstances during the study period, regardless of whether they are related to the study, you should promptly notify your doctor, who will make a judgment and provide appropriate medical treatment.

You need to complete telephone follow-up on time during the research period, which may take up some of your time and cause inconvenience to you.

7. Confidentiality of Personal Information and Medical Records

All records related to your identity are confidential,and your name will not appear in the caserecord form, any relevant research reports, and public publications. Your medical records (research medical records/CRF, laboratory tests, etc.) will be kept intact at the hospital where you visit. The doctor will record the results of laboratory tests in your hospitalization or outpatient medical records. Only researchers, sponsors, monitors, ethics committees, and drug regulatory authorities have the right to access all of your research records when necessary. We will make every effort to protect the privacy of your personal medical data within the scope permitted by law.

You have the right to access information and materials related to yourself at any time during the research period.

8. How to Obtain More Information?

During the research process, if you have any questions or misunderstandings related to this study, you can always raise them with the physician responsible for the study. Your doctor will leave you his/her phone number so that he/she can answer your question.

If there is any important new information during the research process that may affect your willingness to continue participating in the study, your doctor will notify you promptly.

9. You can Voluntarily Choose to Participate in The Study or Withdraw From The Study Midway

Whether to participate in the study depends entirely on your willingness. You may refuse to participate in this study, or withdraw from this study at any time during the study process, which will not affect your relationship with the doctor, will not result in discrimination or retaliation, and will not affect your medical treatment and rights.

For the best interests of you, if you require additional treatment, fail to comply with the study plan, or experience injury related to the study or for any other reason, the study physician may

terminate your participation in this study.

If you withdraw from the studyfor any reason, you maybe asked about your use of the study drug. If the doctor deems it necessary, you may also be required to undergo relevant laboratory and physical examinations.

Informed Consent Signature Page

I have read the above introduction about this study and have the opportunity to discuss and raise questions with doctors regarding this research. All the questions I raised have received satisfactory answers.

I am aware of the potential risks and benefits associated with participating in this study. I am aware that participating in the study is voluntary, and I confirm that I have sufficient time to consider it and understand:

1. I can ask the doctor for more information at any time.

2. I can withdraw from this study at any time without discrimination or retaliation, and my medical treatment and rights and interests will not be affected.

3. If I need to take other treatments due to changes in my condition, I will seek the doctor's opinion in advance or truthfully inform them afterwards.

4. If I fail to comply with the research plan, or if there is any injury related to the study or for any other reason, the research physician may terminate my participation in this study.

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

Finally, I have decided to agree to participate in this study and ensure that I follow medical advice as much as possible.

Subject 's Name:_____ Subject 's Signature: _____

Date of Signature: _____

Contact Phone: _____ Mobile: _____

Doctor's Statement

I confirm that I have fully explained the detailed information of this study to the subjects, including their rights, potential benefits, and risks, and provided them with a signed copy of the informed consent form.

Name of Researcher: _____ Researcher's Signature:_____

Date: _____ Work Phone: _____; Mobile: _____

(Note: If the subject is illiterate, a witness's signature is required. If the subject is incapable, a legal representative's signature is required.)