Informed Consent Form

Project Name: Early identification of Malignant Brain edema in laRge Artery oCclusive stroke after Endovascular therapy (EMBRACE study).

Informed Consent Form Version Number and Date: 1.0, March 20, 2024

Dear Participant,

We invite you to participate in the "Early identification of Malignant Brain edema in laRge Artery oCclusive stroke after Endovascular therapy (EMBRACE study)" which has been approved by Zhejiang Provincial People's Hospital. The study will be conducted in Zhejiang Provincial People's Hospital, Aksu People's Hospital, Wenling People's Hospital, and 2 other hospitals, with an expected participation of 1950 volunteers, of which Zhejiang Provincial People's Hospital is expected to have 1450 participants. This study has been reviewed and approved by the Ethics Committee of Zhejiang Provincial People's Hospital.

This document will provide you with information to help you decide whether to participate in this study. Your participation in this study is entirely voluntary, and your decision will not affect your normal medical treatment rights and benefits at this hospital. If you choose to participate in this study, our research team will do its best to ensure your safety and rights during the study process.

This document provides you with information to help you decide whether to participate in this clinical study. Please read it carefully and if you have any questions, please raise them to the researcher in charge of this study.

I. Purpose of the Study

Since 2015, multiple multicenter randomized controlled trials have provided evidence supporting the application of endovascular treatment (EVT) for acute large vessel occlusion ischemic stroke. However, about 20% of patients may develop malignant brain edema (MBE) after EVT, which diminishes the benefits of EVT. The role of routine medical drug treatment is limited, and early decompressive craniectomy has been proven to be the most effective treatment, and delayed surgery may lead to irreversible outcomes. Therefore, effectively identifying high-risk patients for MBE after EVT can help clinicians make appropriate triage and early intervention decisions as soon as possible, thereby saving patients' lives.

Since MBE involves various complex pathological mechanisms, single factor is difficult to predict the occurrence of MBE, establishing a multifactorial prediction model for MBE after EVT can help clinicians identify high-risk patients for early MBE and timely adjust treatment strategies or early decompressive craniectomy surgery.

The purpose of this study is to use patients' baseline clinical and imaging characteristics to construct a model to predict high-risk patients for MBE after EVT and to externally validate the model in the real world.

II. Research Process

You will undergo CT or MR perfusion examination before treatment and calculate the hypoperfusion volume and core infarction volume. If you meet the indications for EVT, the main team will inform you and you or your legal guardian will decide whether to undergo EVT. If you participate in this study, we will closely monitor and assess your neurological function after EVT, and dynamically examine the postoperative edema with head CT; at the same time, we will follow up with you within 3 months after EVT to assess your condition and provide evaluation, explanation, and guidance for your various test indicators.

III. Possible Risks and Discomforts

(1) Allergy to iodinated contrast agents or gadolinium-based contrast agents (see the informed consent for the use of contrast agents); if an allergic situation occurs, the radiology medical staff will immediately implement corresponding rescue measures;

(2) The risks associated with EVT

① Intracranial hemorrhage during or after thrombectomy, with corresponding symptoms, sometimes requiring surgical treatment, which can lead to death in severe cases; ② Reperfusion injury and brain edema after thrombectomy, which can lead to coma and death in severe cases, and sometimes requires craniotomy for

decompression; ③ If thrombectomy is not successful, the patient's symptoms cannot be relieved; ④ The patient can have another stroke after treatment; ⑤ The condition varies with each patient, and various unexpected situations may occur during or after EVT, which can be life-threatening in severe cases;

If any of the above situations occur, the doctor will take corresponding rescue measures according to the standard guidelines;

(3) Some patients who do not like confined spaces may feel uneasy in the semi-enclosed CT or MR scanning room, and if they really cannot bear it, we will consider terminating the examination.

IV. Expected Benefits

During the study process, we will comprehensively assess and monitor your relevant neurological function indicators to further provide you with an individualized treatment plan.

V. Alternative Treatment

If you do not wish to participate in this study, you may choose not to participate, and you will enter the normal clinical diagnostic and treatment process, which will not affect your routine clinical treatment.

VI. Cost Explanation

This study is a prospective observational study and will not bring additional costs to your treatment. The costs you bear will not change. We will provide you with free dynamic neurological system monitoring assessment and follow-up consultation after discharge, but the costs you bear during the intravenous thrombolysis, EVT, and standard guideline drug treatment process will not be additionally exempted.

VII. Compensation

If the patient develops edema and bleeding after surgery, active treatment will be provided, and compensation for increased treatment costs due to study-related injuries

will be provided (depending on the degree of relevance to this study).

VIII. Confidentiality

Any information obtained about you during the study will be kept in the hospital according to regulations and strictly confidential, and will only be used for this study. Any public reports on the results of this study will not disclose your personal identity information. We will do our best to protect the privacy of your personal medical records within the scope of the law.

In necessary situations, researchers, research authorities, ethics committees, and higher-level inspection departments will be allowed to review your medical records and related information under the premise of signing a confidentiality agreement. When you sign this informed consent form, it means you agree to use your personal and medical information for the purposes described above.

IX. Voluntariness

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

If you need other treatments, or if you do not follow the study plan, or if you suffer any study-related injuries or for any other reasons, the research physician can terminate your continued participation in this study.

X. Participant Obligations

As a research participant, you have the following responsibilities: to provide truthful information about your medical history and current health status; to inform the research physician of any discomfort you experience during this study; to inform the research physician whether you have participated in other studies recently or are currently participating in other studies.

XI. Contact Information

You can always understand the information and progress of this study, and if there is any new safety information related to this study, we will also 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 process, if you have any questions or demands about your rights to participate in this study, you can contact the Ethics Committee of Zhejiang Provincial People's Hospital, contact number: 0571-85893643.

Informed Consent Signature Page

□ I have read the above introduction regarding this study, and the research physician has explained the study content to me in detail. I have no further inquiries about the study before signing the informed consent form. Based on this, I voluntarily participate in the clinical study introduced in this document, and my decision is based on a full understanding of the potential risks and benefits associated with participating in this study. Furthermore, the researcher has not used deception, inducement, coercion, or other means to force me to agree to participate in the study, and I know that I can withdraw from the study at any stage without conditions.

□ The participant is unable to act or has limited ability to act, and this informed consent is signed by his/her guardian or legal representative.

Participant's Signature: Legal Representative's Signature:

Date: Date:

Participant's Contact Information: Legal Representative's Contact Information:

Guardian's Signature: Fair Witness's Signature:

Date: Date:

Guardian's Contact Information: Fair Witness's Contact Information:

I have accurately informed the participant of this document, he/she has accurately read this informed consent form, and has had the opportunity to ask questions.

Researcher's Name:

Researcher's Signature:

Date:

(Please note: If the participant is illiterate, a witness's signature is required. If the participant is unable to act, a representative's signature is required.)