Informed consent form

Efficacy and Safety of Butylphthalide for Acute Ischemic Stroke Patients Receiving Intravenous Thrombolysis or Endovascular Treatment (BAST) Trial

You will be invited to participate in a clinical study, which is sponsored by Beijing Tiantan Hospital, Capital Medical University, and conducted in about 30 hospitals of China. This informed consent gives you some information to help you decide whether to participate in this clinical study or not. Please read it carefully. If you have any questions, please ask the researchers responsible for the study.

Your participation in this study is voluntary. This study has been reviewed and approved by the Ethics Committee of Beijing Tiantan Hospital and all the participating sites. If you have questions related to the subjects’ rights and interests, please contact the Ethics Committee of Beijing Tiantan Hospital at 010-67098551.

1. Purpose of the study: As a neuroprotective medication, butylphthalide (NBP) may help to protect against cerebral ischemic injury. However, evidence about whether NBP influences the outcomes of patients with acute ischemic stroke who are receiving revascularization treatment is limited. This study aims to evaluate whether additional NBP therapy can improve the functional outcome of patients who receive intravenous recombinant tissue plasminogen activator and/or endovascular treatment (EVT).

2. Process of the study: If you agree to participate in this study and sign the consent, we will number each participant and create a medical record file. You will be randomized at a 1:1 ratio to receive either NBP or placebo daily for 90 d alongside standard intravenous rt-PA and/or EVT, which will include 14 d of injections and 76 d of capsules. You will be visited on phone at 30 d and 60 d, and face-to-face at 90 d to collect your health condition according to medical scales.

3. Risk and discomfort: Possible risks of the study might be allergy to NBP or placebo and other adverse reactions including hepatic injury, nausea and psychiatric symptoms. In case of complications, we will take appropriate measures for
treatment in a timely manner. You can receive free treatment and/or compensation if there is any harm associated with the clinical study, and you also have the right to suspend treatment at any time.

4. Benefits received as a participant: The result of the study will give an answer to the question that whether NBP will improve the functional outcome of patients who receive intravenous recombinant tissue plasminogen activator and/or EVT. Besides, your health condition will be closely monitored by the doctor and all the NBP or placebo used during the study will be free of charge.

5. Responsibilities should be followed as a participant: Once participate in this research, you have the responsibility to provide true information about your medical history and current physical condition. Take the study drugs as instructions, and not to take restricted drugs. Inform your study doctor timely of any discomfort during the study period.

6. Privacy issue: If you decide to participate in this study, your personal data and during the study are confidential. All your information will be identified by a study number rather than your name, and will not be disclosed to anyone other than the members of research group. To ensure that the study is conducted in accordance with the regulations, if necessary, members of the government management department or the ethics review committee may refer to your personal data in the research as required. When the results of this study are published, no information about you will be disclosed.

You may choose not to participate in this study, or at any time inform the researcher to request withdrawal from the study. Your data will not be included in the study results, and any medical treatment and benefits will not be affected.

If you need additional treatment, or if you don't follow the study plan, or if you have any injuries related to the study or for any other reason, the investigator may terminate your continued participation in the study.

Signature for Consent
I have read an informed consent form.
I have the opportunity to ask questions and all questions have been answered.
I understand that participation in this study is voluntary.
I can choose not to participate in this study, or quit at any time after informing the researcher without any discrimination or reprisals, and my medical treatment and rights will not be affected.
If I need other treatment, or if I don't follow the study plan, or if there is any injury related to the study or if there is any other reason, the research physician may terminate my involvement in this study.
I will receive a signed copy of the informed consent.

Patient's name: __________________________
Signature of patient: ________________________
Signature of the agent of patient: ______________________
Date: ________________________
I have accurately informed the subject of this document that he/she has read this informed consent and has demonstrated that the subject has the opportunity to ask questions. I certify that he/she consented voluntarily.

Researcher's name: __________________________
Signature of researcher: ________________________
Date: ________________________