Official Title A prospective multicenter clinical study of aspirin for prophylaxis in patients with hereditary or acquired thrombotic thrombocytopenic purpura

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Informed Consent Form for Subjects
(Informed Consent Form)

Prospective Multicenter Clinical Study of Aspirin for Prevention in Patients with Hereditary or Acquired Thrombotic Thrombocytopenic Purpura Dear Ms./Mr.

You are being invited to participate in a clinical study. The following items describe the background of the study, the purpose of the study, the methods of the study, the benefits and possible discomfort and inconvenience of the study, and your rights and interests, and should be read carefully before you participate in the clinical study. This informed consent form provides you with information to help you decide whether to participate in this clinical study. If you have any questions, please ask the physician in charge of the study to ensure that you fully understand the content. Your participation in this study is voluntary. If you agree to participate in this clinical study, please sign the signature page of the informed consent form.

I. Background of the study

Thrombotic thrombocytopenic purpura (TTP) is a rare and life-threatening thrombotic microangiopathy characterized by thrombocytopenia, microangiopathic hemolytic anemia, and microvascular thrombosis causing neurological and renal abnormalities; it is associated with massive depletion of platelets in the microvasculature to form microthrombi1 . Long-term follow-up of patients with cTTP revealed frequent strokes and renal injury. Of 217 surviving patients, 62 (29%) had a stroke; the median age was 21 years. iTTP patients also require long-term follow-up. iTTP patients with low ADAMTS13 activity (<70%) in remission have a 28% risk of stroke. Survival rates of iTTP patients in remission were lower than those of age-, race-, and sex-matched populations. In terms of stable treatment, maintenance therapy is not recommended for patients with iTTP. Previous studies have shown that aspirin may be able to prevent stroke complications in patients with cTTP and iTTP. In addition to its potential efficacy, the risks of aspirin are small and inexpensive. Aspirin is very effective in secondary prevention of stroke 6. However, the therapeutic value of aspirin in TTP has not been studied previously. To improve the prognosis and survival of patients with cTTP and iTTP, we propose to conduct a prospective study to observe the efficacy and safety of aspirin in patients with cTTP and iTTP in remission.

II. Study name and purpose

This is a prospective clinical trial study to investigate the efficacy and safety of aspirin on complications in patients with cTTP and patients in remission after an episode of iTTP.

III. Study methods and content

The study is a multicenter, open, randomized, controlled, prospective study with an expected study duration of 3 years. 150 subjects with TTP in remission are planned to be included in the experimental and control groups in a 1:1 ratio. Patients were randomly assigned to each experimental group and numbered according to the envelope method.

Experimental group: aspirin 100 mg QD orally for prophylaxis during TTP remission

Control group: administered with corresponding placebo orally.

IV. Study procedure and time frame

The efficacy was assessed within 3 years after treatment, and the assessment indexes included MRI imaging evidence, cognitive function analysis, and psychoneurological symptoms.

V. Possible benefits of participating in the study

With this study, aspirin is a free gift and MRI testing is provided free of charge after aspirin administration for each patient, this study may be beneficial to improve the prognosis of TTP, potentially providing benefits for other patients in the future.

VI. Possible risks and discomforts of participating in the study

Aspirin may increase bleeding tendency during application due to inhibition of platelet aggregation; it may damage the mucosa of the digestive tract and even cause ulceration and bleeding of the gastric mucosa. Aspirin is a safe small-molecule drug, and in a few cases, if the above-mentioned adverse reactions occur in a small number of patients, they can be recovered by stopping the drug. If a very small number of patients do not recover completely from discontinuation of the drug, we can provide therapeutic support.

VII. Treatment and financial compensation for subjects with study-related injuries

In case of study-related injuries, the study sponsor will bear the relevant medical treatment costs and corresponding financial compensation according to the relevant laws and regulations of China.

VIII. Conventional treatment plan outside the study

None.

Subjects rights

Subjects rights to participate in the study include voluntary participation and withdrawal at any time, informed participation, consent or non-consent, confidentiality, compensation, free treatment and compensation in case of damage, no discrimination or retaliation at any time after withdrawal, and medical treatment and rights will not be affected as a result.

X. Confidentiality of clinical research data

The information and data recorded by the subjects participating in the study will be kept strictly confidential and will not be disclosed, and if the study results are published, the subjects identity information will also be kept confidential.

XI. Collection and management of biological samples involving human subjects

3ml of peripheral blood will be collected from the subjects each time according to the follow-up plan, separated from the routine examination, without additional collection times, mainly for immune cell biology analysis and translational medicine research, and the specimens will not be used for product development, sharing and secondary use, etc., and privacy protection, destruction and disposal will be strictly observed.

XII. Contact information

Contact person and contact information of the investigator (contact person: Qi Jiaqian, contact information: 18913091817), contact person and contact information of the ethics committee (contact person: Wu Shangejie, contact information: 0512-67972743), contact person and contact information in case of problems.

XIII. Declaration and signature

Subject declares that I have read this informed consent form carefully and that I have had the opportunity to ask questions and that all questions have been answered. I understand that participation in this study is voluntary and that I may choose not to participate in this study or withdraw from the study at any time with notice to the investigator without discrimination or reprisal, and that any of my medical treatment and rights will not be affected as a result.

If I require other treatment, or if I fail to comply with the study plan, or for any other valid reason, the study physician may terminate my continued participation in this clinical research study.

I voluntarily agree to participate in this clinical study, and I will receive a signed copy of the "Informed Consent" form.

Subjects name (in block letters);
Subjects signature:
Date: Month and year:
Mobile phone number:
Name of legal representative (in block letters):
Signature of legal representative:
Date: Month and year.
Mobile phone number:
Relationship to subject:
Subjects reason for not being able to sign informed consent:

The investigator declares that I have accurately informed the subject of the contents of the informed consent form and have answered the subjects questions, and that the subject is voluntarily participating in this clinical study.

Investigators name (in block letters):
Investigators signature:
Date: Month and year:
Mobile phone number: