

Cerebral Venous Thrombosis Cohort Study in China Mainland

Informed consent version date: 4/16/2019

Dear Sir/madam,

The symptoms you suffered are caused by a disease called “cerebral venous sinus thrombosis (CVST)”. CVST is caused by a clot in the venous sinus of the brain, which resulted in an obstruction of the blood outflow. Because of this obstructed blood flow, certain functions of the brain can be affected. The treatment of this disease includes anticoagulation, thrombolysis and thrombectomy. Most patients make a good recovery. However, some patients may suffer from adverse event.

At this moment, a clinical trial is going on to record the patients' clinical characteristics, laboratory indices, radiology examinations and treatment strategies, in order to provide a reference for clinicians. This is a nationwide trial in which your region is coordinated by the hospital you were admitted in. This trial has been approved by the medical ethics committee of your hospital.

We would like to ask you to participate in this trial. Before you decide to you collaborate, it is important for you to know more about this trial. Therefore, we kindly request you to carefully read this information and discuss it with your partner, friends or family. If you have any additional questions, you can ask your physician or the

investigators in your hospital. At the end of this document you can find their contact data. You'll also find the name and data of an independent physician, who is not involved in this trial, where you can obtain additional information.

Since this trial is an observational study, there will be no influence on your treatment. No additional risk will be caused by this trial and no risk insurance covers this trial. Participation with this trial is free of costs. You or your physicians will not be reimbursed for your participation.

Your data will be treated as confidential. Personal data will be replaced by a unique code number. Only personnel involved in performing this trial have access to this code. Health authorities who are authorized to check whether this trial is carried out correctly and in agreement with the legal standards, may have access to your medical files. The results will be published in a scientific medical journal. When the results of the trial will be published, your personal data will remain hidden and secret.

Before the treatment starts, your physician will have to obtain your clinical data as baseline. This will take you a couple of minutes to fill in some forms. At 1, 3, 6 and 12 months after the beginning of the CVST, you will be checked at the outpatient department. Here again some questionnaires will be filled out to assess the degree of recovery you

have made. This will take no more than 15 minutes. When the questionnaire at 12 months has been filled out, the trial is ended for you.

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Independent physician

Name:

Address:

Telephone number:

E-mail:

The decision whether to participate or not is entirely yours. Participation is voluntary. If you do not wish to participate, there is no need to give any reason for that decision. Also, if you decide to participate in this trial, you can withdraw your participation at any moment. If you decide to withdraw, all data which are recorded for the purpose of the trial will be destroyed.

Declaration of participation

I herewith confirm that I have read the information letter about the trial and that I understand the information.

I have had enough time to think about my participation, and I had an opportunity to pose questions. These questions have been answered to my full satisfaction.

I agree to participate in the above mentioned clinical trial.

I know that my participation is completely voluntary, and that I can withdraw my permission at any moment, without having to give a reason.

I herewith give permission to inform my general physician and/or my currently treating physicians about my participation in this trial.

I herewith give my permission to members of the medical committee, the health authorities and the monitor of the study to have access to my medical data and to all the data regarding this trial.

I herewith give permission to use the anonymized data concerning my disease for the purpose of this trial, as described in the information letter.

I am informed that I can be approached for the additional follow up examinations, for which I herewith give permission.

Patients name: _____

Patient telephone number: _____

Date: _____

Signature: _____