

Supplementary file 2

Informed Consent

Version 1.3

Date: 2017.12.28

INFORMED CONSENT

Choice of ANesthesia for EndoVAScular Treatment of Acute Ischemic Stroke at Posterior Circulation (CANVAS II)

Project entrust organization: Beijing Tian Tan Hospital, CMU

Contract Research Organization: N/A

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28th, Dec, 2017

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INFORMATION SHEET

You have been diagnosed with ***acute ischemic stroke in posterior circulation*** and you will receive emergency endovascular treatment.

We would like to invite you to participate our study, which is "***Choice of ANesthesia for EndoVAscular Treatment of Acute Ischemic Stroke at Posterior Circulation***", to observe the effect of general anesthesia and conscious sedation on clinical outcome. This study is approved by Ethics Committee of Beijing Tiantan Hospital of Capital Medical University. During our study, we will follow the Declaration of Helsinki.

Before you decide whether participate this clinical trial, please take time to review this information carefully. This form describes the purpose, procedure, study duration, risks and possible benefits of participating the study. You may also wish to talk to others, including your friends, family, or discuss with your anesthesiologist, about your participation in this study.

1. PURPOSE of THIS STUDY

In China, cerebrovascular disease is the first cause of death. For acute ischemic stroke patients, endovascular therapy is a very important supplementary treatment to improve neurological outcome, in case of thrombolytic therapy failed. Factors associated with clinical outcome of acute ischemic patients including baseline, comorbidity, onset to treatment time and so on. Observational studies indicated that, compared to general anesthesia, conscious sedative ischemic stroke patients may have lower death, better neurological improvement. This indicated that management of anesthesia may effect neurological outcome. However, the research about relationship between acute ischemic stroke and anesthesia management is merely focus on anterior circulation population, while posterior circulation ischemia account for a large amount of stroke and prospective research is need to demonstrate the association between anesthesia management and neurological outcome.

2. NUMBER of PARTICIPANTS

In total, 88 patients will be included in the study.

3. DURATION OF THIS STUDY

This study will last 3 years and we will collect your postoperative information until 90 days postoperatively.

4. PROCESS OF THIS STUDY

If you are willing to participate in the study, please sign this informed consent, and you will be examined including:

- Physical examination and medical history inquiry
- Vital signs: respiratory, body temperature, heart rate, blood pressure.
- Neurological scales: cognitive function, delirium, living quality as well as physical status

- Blood test
- Electrocardiography

If you met the inclusion and exclusion criteria, neuro-radiologist as well as anesthesiologist will evaluate your safety and with the agreement of both of them, you could be allocated into two groups randomly. With the computer-generated table, you will be randomly allocated to receive one of anesthesia management in an equal chance. We will implement your anesthesia according to your group. During the whole study, we will collect your response to different anesthesia methods and your health status through closely intraoperative monitoring. This study will compare your post-treatment neurological outcome, complication, to find out which anesthesia treatment is better for acute posterior circulation ischemic patient, and finally to optimize treatment of patients as you.

5. THE DIFFERENCE OF TWO ANESTHESIA MANAGEMENT

There are most common clinical used anesthesia treatment for your condition, general anesthesia and conscious sedation. However, considering there is no clinical trial to answer this question, it is still unclear which treatment is better. According to experience, general anesthesia may supply a safer airway management. Compared to conscious sedation, you may have a lower chance of respiratory dysfunction for secured airway. Nevertheless, general anesthesia has a higher chance of circulation fluctuation and higher chances of intraoperative hypotension. Moreover, conscious sedative patients are awake during the procedure and be able to do neurological evaluation at any time, to assess the neurological status. Conscious sedative patients may under light agitated status and unable to complete surgery. Therefore, we still unable to answer the question which treatment is better. In conclusion, the purpose of this study is to find out which anesthesia treatment is better for acute posterior circulation ischemic stroke patients and finally to improve the treatment you future patients.

6. OTHER TREATMENT CHOICE

In clinical practice, the anesthesia management for acute stroke patients includes general anesthesia and conscious sedation. If you do not participate in this study, you can choose your anesthesia treatment according to your anesthesiologist's suggestion.

7. WHO SHOULD NOT PARTICIPATE in the STUDY

If you have following condition, you should not participate in the study:

- 1) Anterior circulation occlusion
- 2) $GCS \leq 8$,
- 3) Intracranial hemorrhage
- 4) Seizure or severe agitation
- 5) Intubated before treatment
- 6) Unconsciousness
- 7) Known allergy to anesthetics or analgesics
- 8) loss of airway protective reflexes and/or vomiting on admission

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8. POSSIBLE BENEFITS of PARTICIPATING in the STUDY

Your prognosis may or may not improve as a result of participating in this study, and the information from this study will help determine which anesthesia management are safer and more effective in treating other patients with similar conditions of yours.

9. POSSIBLE ADVERSE REACTIONS, RISKS and DISCOMFORT, INCONVENIENCES of PARTICIPATING in the STUDY

The monitoring methods, anesthesia methods, anesthetic drugs and anesthesia maintenance used in this study are all routine clinical practice. It is possible that related discomfort or adverse event will happened during your anesthesia and operation, including respiratory depression, circulation depression, arrest, cardiac arhythm, myocadial infarction, pulmonary embolism, drug adverse react as well as cerebrovascular complication (hemorrhage and infarction) If you experience adverse reactions or discomfort due to surgical procedures, anesthesia, or changes in your condition during the course of the study, the researchers will make corrections promptly.

During the study, you need to undergo doctors inquiry, laboratory tests and questionnaire, which may cause inconvenience to you.

10. CONFIDENTIALITY of PERSONAL INFORMATION

Your medical records (study records /CRF, lab sheets, etc.) will be kept intact at the hospital. Your doctor will record the results of tests and other tests on your medical record. Researchers, ethics committees, and drug regulators will be allowed access to your medical records. Any public reports on the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical data within the law.

11. HOW TO GET MORE INFORMATION?

You can ask any questions about this study at any time and get answers. Your anesthesiologist will be ready to answer any of your questions before, during and after the study.

12. RELATED EXPENSES

Anesthetic drugs and surgical procedures are not free of charge. If you combine the treatment and examination required for other diseases, and if the treatment fails, the cost of changing to other treatment is not free of charge. If any medical expense happened due to adverse event, you will be exempted from the charge.

13. YOU MAY VOLUNTARILY CHOOSE TO PARTICIPATE in the STUDY and WITHDRAW from the STUDY

Whether to participate in the study is entirely up to you. You may refuse to participate in the study or withdraw from the study at any time during the study, which will not affect your relationship with your doctor or affect your medical service or other benefits.

Before making decision, you can discuss with your family or friend, or you can talk with your doctor for any question, until you fully understand this study.

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14. HOW THE STUDY MAY EFFECT YOUR LIFE?

You may feel the visit and examination uncomfortable and special arrangement is needed. You can consult your doctor in any steps of the study.

15. CONSULTING

If you have any related questions, please contact Dr.Liang Fa (phone: 010-67096658 or cell phone:18810084538).

If you have any concerns about your personal benefit, or you want to complain or express your concerns about the study, please contact the Ethics Committee of Beijing Tiantan Hospital of Capital Medical University (phone: 010-67098555).

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SIGNATURE PAGE of AGREEMENT

Study title: Choice of ANesthesia for EndoVAscular Treatment of Acute Ischemic Stroke at Posterior Circulation

Principal investigator: Ruquan Han, Beijing Tiantan Hospital, CMU

DECLARATION of CONSENT

I have read the introduction about the study above and have the opportunity to discuss with doctors and ask the questions about the study. All my questions have been answered satisfactorily.

I am aware of the possible risk and benefits of participating in this study. I know that participating in the study is voluntary. I have taken it into full consideration, and known that:

- I can ask my doctor for more information at any time.
- I can withdraw from this study at any time without discrimination or retaliation, and my medical treatment and rights will not be affected.

I am also aware that if I withdraw from the study, especially if I withdraw due to medication, it will be of great benefit to the whole study if I tell my doctor about my condition and complete the corresponding physical examination and physical and chemical inspection.

If I need to take any other medication due to a change in my condition, I will consult my doctor beforehand or tell him afterwards truthfully.

I agree that the ethics committee of the drug regulatory authority or the representative of the sponsor may have access to my research information.

I will be provided with a signed and dated copy of the informed consent.

In the end, I agreed to participate in the study and promised to follow my doctors advice as much as possible.

Signature of patient/legal relative: _____

Relation: : _____

Date: _____ (yyyy/mm/dd)

I confirm that I have explained the details of the trial to the patients, including its rights and possible benefits and risks, and have given them a signed copy of the informed consent.

Aignature of doctor: _____

Date: _____ (yyyy/mm/dd)