Human Urinary Kallidinogenase Improve Short Term Motor Functional Outcome By Reducing The Corticospinal Tract Damage In Acute Ischemia Stroke Patients

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Date：2019.07.15

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Informed Consent

1. Project introduction

- **Project name:** Human urinary kallidinogenase improve short term motor functional outcome by reducing the corticospinal tract damage in acute ischemia stroke patients
- Human urinary kallidinogenase is a new class of drugs in China. It has a certain neuroprotective effect, inhibits neuronal apoptosis and acts as nerve repair, which can promote nerve fiber regeneration and improve prognosis.
- **Objective:** To evaluate of the effect of human urinary kallikrein on corticospinal tract injury in ischemia stroke patients.
- **Inclusion Criteria:** (1) 18 years old ≤ age <80 years old; (2) within 72 hours of onset; (3) diagnosed as acute cerebral infarction, and confirmed by magnetic resonance imaging as an acute infarct in the unilateral corticospinal tract; (4) The patient's onset muscle strength grade <4; (5) no history of cerebral infarction or residual physical activity disorder; (6) no other intracranial lesions; (7) patients or their legal representatives voluntarily Sign the informed consent form.
- **Exclusion Criteria:**(1) intracranial hemorrhagic disease: cerebral hemorrhage, subarachnoid hemorrhage, etc.; (2) transient ischemic attack; (3) intravenous thrombolysis and interventional thrombectomy; (4) serious physical illness affects limb movement before enrollment; (5) Apply other drugs with nutritional nerves and regeneration during the study period; (6) Unstable vital signs, severe liver and kidney diseases or malignant tumors; (7) Incomprehensible or incapable of obeying the research procedure or being unable to follow up due to mental illness, cognitive or emotional disorders;
- **Study process:** This study is expected to last for 2 years. At the time of admission and after 14±5 days of treatment, the diffusion tensor imaging(DTI) is performed to evaluate the nerve fiber damage and about 5 ml blood samples will

be collected each time, which will be conduct related proteomics tests at the Second Hospital of Hebei Medical University, and you will get relevant results after the study. The cost of testing is borne by the project funds.We will keep an eye on your physical recovery and your health throughout the study.

- If you are willing to participate in this study, you will have an equal opportunity (50%) to be assigned to the experimental or control group. The basic treatment of both groups is based on the 2016 edition of the Guidelines and Consensus for the Diagnosis and Treatment of Chinese Cerebrovascular Diseases. If you are in the thrombolysis time window, you can choose to have intravenous thrombolysis.

2. Research units and personnel

Department of Neurology, Second Hospital of Hebei Medical University;

Xiaoyun Liu, Chief Physician, Department of Neurology, Second Hospital of Hebei Medical University;

Peifang Li, Master of Neurology, Second Hospital of Hebei Medical University;

Kun Zhang, Ph.D., Department of Neurology, Second Hospital of Hebei Medical University;

Xiaoman Shi, Master of Neurology, Second Hospital of Hebei Medical University;

Jing Tian, Master of Neurology, Second Hospital of Hebei Medical University;

Tong Li, Master of Neurology, Second Hospital of Hebei Medical University;

3. Research benefits:

1. The research doctor will systematically pay close attention to your changes in the condition, and give the subjects detailed individual medication and exercise guidance to promote limb recovery; 2. During the visit, the research doctor assists the patient to make an appointment check, and accepts the patient's consultation free of charge, facilitating the patient's review and exempting the registration fee.

4. The study may present discomfort and risk to the subject:

The main risk of subjects participating in the study was the use of research drugs for adverse reactions such as vomiting, facial flushing and facial fever, headache, diarrhea, conjunctival hyperemia, palpitation, chest tightness, and itching at the injection site, but generally lighter, no special treatment is required.There may be individual patients who may be particularly sensitive to kallikrein and have a blood

pressure drop. When the above situation occurs, relevant treatment or withdrawal will be given in time.

5. About the cost of participating in the trial:

You are not required to pay an additional fee in addition to the regular related medical expenses for the illness of the subject.The costs of the drugs and laboratory tests not related to this study need to be paid normally. If the subjects need to combine the treatment and examinations required for other diseases, and the cost of switching to other treatments due to ineffective treatment, normal payment is also required.

6. If I do not participate in this study, do I have other treatment options?

Participation in this study may improve or not improve the health of the subject. If the subject does not participate in the study, you may still receive standard treatment based on the stroke guidelines.

7. Confidentiality of the study:

The subject's records will be kept in a safe and confidential manner, and the relevant clinical data and various test results of the subjects will be applied to anonymous paper presentations and conference exchanges. Subject information may be subject to surveillance by the relevant authorities (Ethics Committee, Food and Drug Administration), but will not disclose the identity of the subject.

8. Related consultation:

If you have any questions related to this study, contact the doctor: Peifang Li Contact: 15203216570

9. Subject's rights:

Participation in the study is completely voluntary, the subject can refuse to participate in the study, or withdraw from the study at any time without any reason, and the withdrawal from the trial will not have a loss of equity or any punishment. And the decision does not affect the doctor's treatment of the subject.

The trial protocol was approved by the ethics committee and there were any violations of the study protocol during the trial. Subjects could complain directly to the hospital ethics committee. Contact telephone 0311-66002812.

I have read the informed consent form of this clinical trial in detail. My doctor has

given me a detailed description of the protocol. I fully understand the purpose, nature, methods and my rights and risks of this research. I understand that my personal information is confidential and my privacy can be protected.

I volunteered to participate in this study and agreed to follow the research method and cooperate with the doctor to complete the study.

This informed consent is 3 pages in total and I will get a copy of the signed informed consent form.

Subject signature: _____

Signature of the legal representative of the subject (if necessary):_____

Date:_____

I have fully explained to the subject the purpose of the clinical trial, the course of operation, and the potential risks and benefits that the subject may have in the trial, and satisfactorily answered all relevant questions of the subject.

Signature of the principal investigator or his designated researcher (informer to the subject):_____

Date:_____