A prospective, multicenter, randomized and open study comparing the efficacy and safety of KHA80 hemoperfusion combined with hemodialysis with routine hemodialysis in removing IL-6, β2-MG and PTH in maintenance hemodialysis patients

March 14th, 2023

Informed consent informed page

Dear Sir/Madam,

Hello! We will invite you to participate in a clinical study: a prospective, multicenter, randomized and open study comparing the efficacy and safety of KHA80 hemoperfusion combined with hemodialysis with routine hemodialysis in removing IL-6, β2-MG and PTH in maintenance hemodialysis patients. This study was initiated by the First Affiliated Hospital of Fujian Medical University. In order to protect your rights and interests, the research plan and informed consent of this study have been approved by the Ethics Committee. It is very important for you to read and understand this informed consent form before agreeing to participate in this research. This document explains to you the purpose, steps, possible benefits and risks of this study. At the same time, it also explains to you other treatments available to you and your rights. Please read it carefully, and if you have any questions, please ask the researcher in charge of the study. Your participation in this study is voluntary and you can withdraw from the study at any time. If you decide to participate in this research, you will get a copy of the informed consent signed by both parties.

First, the research purpose

Jianfan KHA80 hemoperfusion device is a special hemoperfusion device for maintenance hemodialysis patients, which can remove uremic macromolecular toxins represented by β2 microglobulin (β2-MG). According to the experimental data in vitro, the clearance rates of KHA series for interleukin -6(IL-6) and parathyroid hormone (PTH) can reach 64.6% and 86.9%, respectively. Moreover, through the scientific design of the column structure, it can save the clinical operation time, provide a better operation experience, ensure the safety and effectiveness of clinical use, and make the clinical operation more in line with the latest SOP requirements issued by the state. This study will observe the effects of hemodialysis combined with hemoperfusion on IL-6, β2- microglobulin and PTH in uremia patients through a multicenter, prospective, randomized and open controlled study, aiming at evaluating the effectiveness and safety of Jianfan KHA80 hemoperfusion device, and providing basis for future clinical application and guideline formulation.

Second, the research content and process

If you agree to participate in this study, we will number each subject and randomly assign them to the hemodialysis or hemodialysis filtration treatment group (197 cases in total, the treatment

frequency is ≥2 times/week), and randomly assign them to the hemodialysis or hemodialysis filtration treatment to receive Jianfan KHA80 hemoperfusion treatment (197 cases in total, the hemodialysis or hemodialysis filtration treatment frequency is ≥2 times/week, and the hemoperfusion treatment frequency is ≥2 times). Our study will last for 52 weeks and be divided into 6 follow-ups. You will be visited at 0 week, 4 week, 12 week, 24 week, 36 week and 52 week. The researcher will record your condition change, dialysis prescription and treatment, and carry out related physical examination, laboratory examination and auxiliary examination.

Third, the cost of the research.

If you are randomly assigned to Jianfan KHA80 hemoperfusion treatment group on the basis of hemodialysis or hemodiafiltration treatment, your treatment fee will be paid for hemoperfusion treatment and KHA80 hemoperfusion device according to the provisions of provincial and municipal medical insurance or other provincial and municipal medical insurance.

After you join the group, according to the research plan, blood will be collected at 0, 4, 12, 24, 36 and 52 weeks for routine blood examination (hemoglobin, RBC, WBC and platelets), blood biochemistry (including blood calcium, phosphorus, sodium, potassium, albumin, urea nitrogen, creatinine and alkaline phosphatase), blood PTH, blood IL-6 and blood phosphatase. Among them, the blood routine and blood biochemical tests are consistent with the regular testing items of hemodialysis patients required by the state and Fujian hemodialysis quality control center, and the required expenses are paid according to the provisions of provincial and municipal medical insurance or medical insurance in other provinces and cities, and you do not need to bear additional expenses. Blood PTH, IL-6, β2- microglobulin and other items are tested free of charge (the expenses are paid by the researchers). 200 yuan was compensated for each blood collection, and a total of 1,200 yuan was compensated for completing 6 blood collections.

Iv. possible benefits from participating in this study

During the research, experienced research doctors will actively pay attention to the changes of your condition and provide timely and detailed guidance and treatment. You and society may benefit from this research, which includes that your condition may be improved, and this research may help develop a new treatment method for other patients with similar conditions. You will get good medical services during the study. Testing your blood sample will help to diagnose and evaluate your uremia-related complications, provide necessary suggestions for your treatment, or

provide useful information for disease research.

V. Possible risks and discomforts of participating in this study

During the study, any blood purification treatment may have adverse reactions, and all patients who need blood purification treatment should sign the informed consent form of blood purification before the first dialysis. Blood purification treatment has certain risks because it needs to take the patient's blood out of the body for extracorporeal circulation. The possible risks are:

1. Due to the biological incompatibility of the equipment, patients have chills, fever, chest tightness, dyspnea, and transient decrease of white blood cells or platelets.

2. Blood loss due to coagulation dysfunction or cardiopulmonary bypass coagulation.

3. Accidents that may occur in other routine clinical blood purification treatments may occur.

If you have any discomfort, new changes in your condition, or any unexpected situation, whether related to the study or not, you should inform your doctor in time, and he/she will make a judgment and medical treatment.

VI. Compensation and treatment available to you in case of research-related injury.

During the research, if you have any research-related injuries or diseases, you should contact your doctor, who will provide you with necessary medical care and advice.

Under rare circumstances, if you follow the normal procedures stipulated in the study during the study, you will get treatment and corresponding compensation according to the laws and regulations of China and the relevant provisions of this study, and the related treatment expenses will be paid with legal receipts and invoices, but this treatment and compensation is not applicable to any medical accident. Besides the above, there will be no other forms of compensation.

Seven, other treatment interventions

Except for the fixed treatment mode involved in this clinical study, other treatments for your condition, such as hemodialysis and medication, are not affected.

VIII. Confidentiality of research

If you decide to participate in this research, your personal data during the research and participation will be kept confidential. Your blood/urine specimen will be identified by the study number instead of your name. Information that can identify you will not be disclosed to members outside the research team unless your permission is obtained. All research members and research sponsors are required to keep your identity confidential. Your file will be kept in a locked filing

cabinet for researchers' reference only. In order to ensure that the research is carried out in accordance with the regulations, if necessary, members of government management departments or ethics committees can consult your personal data in the research unit according to the regulations. When the results of this research are published, no personal information about you will be disclosed.

IX. Your Rights and Obligations

You can choose not to participate in this study, or notify the researcher to withdraw from the study at any time. Your decision will never affect your relationship with medical staff, and your medical treatment, rights and interests will not be affected, and you will not be treated unfairly and punished. If you decide to withdraw from the study, please be sure to contact your research doctor. If you stop treatment and examination during the study, the research doctor may ask some questions related to your health and may ask you to have some examinations for the purpose of being responsible for your health.

If you need other treatment, or you don't follow the research plan, or your research doctor thinks that it is not in your best interest to continue to participate in this research, the research doctor can let you withdraw from the research; If you feel uncomfortable or have safety risks after using the treatment method of the study, the research doctor or the sponsor may ask you to withdraw from the study without your consent, and the research doctor will discuss with you the relevant matters after you withdraw from the study.

You can know the information and research progress related to this study at any time. If you have any questions related to this study, or if you have any discomfort or injury during the research, or if you have any questions about the rights and interests of the participants in this study, you can contact the medical staff of the Department of Nephrology in the hospital. If you have any questions about your rights as a research participant, you can contact the personnel of the Ethics Committee at.

express one's thanks/gratitude

The development and progress of medical science can not be separated from clinical research. Your participation will contribute to the progress of medical science and the research and

exploration of diagnosis and treatment of this disease. As the sponsor and researcher of this research, we will always remember your contribution and express our most sincere thanks to you.

Informed consent form consent signature page

Before signing this informed consent, I have read the above information and understood the purpose of the project and the potential benefits and risks that may be brought by participating in the project. I confirm that I have been fully considered and have the opportunity to ask questions about the research procedures and methods, and all the questions have been answered to my satisfaction.

I agree that the research doctor collects and processes my information, including information related to my health. I agree that my information (except personal information) will be handled by the applicant or handed over to the company that cooperates with the applicant. If I decide to withdraw from this study, I agree that the information collected before this can still be processed.

I have the right to get consulting services at any time, and I have the right to decide to withdraw from this research plan at any time without any adverse impact and without losing any legal rights. I voluntarily sign this informed consent form, and voluntarily participate in this research project, and will fully cooperate with the researchers. I have got a copy of this document.

The subjects

Name (BLOCK) _ _ _ _ _ _ _ _ _ _ _ _ _ Signature: _
_ _

Tel: _ _ _ _ _ _ _ _ _ _ _ _ _ _ Date: _
_ _

Legal representative/legal guardian

Name (BLOCK) _ _ _ _ _ _ _ _ _ _ _ _ _ Signature: _ _ _ _ _ _ _ _ _ _ Relationship with the subject:
_ _
_ _ _ _ _

Tel: _ _ _ _ _ _ _ _ _ _ _ _ _ Date: _
_ _

An impartial witness statement

I confirm that the information in the consent form has been accurately interpreted and understood by the patient and/or the patient's legal representative, and the consent opinion was voluntarily provided by the patient and/or the patient's legal representative.

Name (BLOCK) _ _ _ _ _ _ _ _ _ _ _ _ _ Signature: _
_ _

Tel: _ _ _ _ _ _ _ _ _ _ _ _ _ _ Date: _
_ _

Note: If the patient, legal guardian or legal representative can't read and sign the consent form (such as severe visual impairment, dyslexia or illiteracy), there must be at least one impartial witness. An impartial witness must be present during the whole process of discussing the informed consent.

I have accurately informed the subjects of the informed consent form and answered their questions, and the subjects volunteered to participate in this clinical trial.

Signature of the researcher: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Tel: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Date: _