Effects of neutrophil gelatinase-associated lipid carrier protein (NGAL) from osteoblasts and vascular smooth muscle cells on vascular calcification and the intervention of Parietal in chronic kidney disease (CKD) informed consent

Before you decide whether to participate in the study, please read the following as carefully as possible. It helps you understand the study and why it is being conducted, the process and duration of the study, and the possible benefits, risks, and discomfort of participating in the study. If you prefer, you can also discuss it with your relatives and friends, or ask your doctor for an explanation to help you make a decision.

I. Research background

Vascular calcification is a common and refractory complication of chronic kidney disease, especially in patients with maintenance hemodialysis. However, there are no effective prevention and control measures. Previous studies suggest that NGAL may be involved in the process of vascular calcification in patients with chronic kidney disease, and parialcitol, a drug for the treatment of secondary hyperparathyroidism in patients with maintenance hemodialysis, may alleviate vascular calcification by inhibiting NGAL.

2. Research objectives

Effect of NGAL on vascular calcification and intervention of Parietalcide.

3. Research process

1. Number of participants: a proposed total of 80 cases.

2. Study content: To observe the effects of parietalcide on blood NGAL level and vascular calcification in patients with maintenance hemodialysis.

3. Specific research steps and methods Information of maintenance hemodialysis patients treated with parietalccitol was collected, routine test and examination data before medication were recorded, and follow-up data were collected at the same time from the beginning of medication 6 months to the end of December, including hospitalization, death, loss of follow-up and other events. Two ml of fasting plasma were collected before, 6 and 12 months after

administration for NGAL detection.

4. Study Duration: 2-3 years.

Criteria for inclusion and exclusion

1. Inclusion criteria: ① Patients with secondary hyperparathyroidism diagnosed as maintenance hemodialysis with blood PTH>300pg/ml; ② Age 18-65;③ There was no pTH-lowering treatment with Parietalcitol within 3 months before enrollment, and it was planned to use parietalcitol injection to treat SHPT;④ Agree to participate in this study.

2. Exclusion criteria: ① Patients allergic to vitamin D or similar drugs; ② Vitamin D poisoning;③ hypercalcemia;④ Chronic disease active stage, acute infectious disease, active liver disease, tumor, had been hospitalized in the last 3 months;⑤ New fracture or major trauma surgery occurred in the last 3 months.

3. Contraindications: ① Patients allergic to vitamin D or similar drugs; ② Vitamin D poisoning;③ Hypercalcemia.

5. Alternative therapy

Hemodialysis patients with secondary hyperparathyroidism may also choose the quality of sinacarcel or calcitriol pills.If you have any questions about treatment options related to your disease, please consult your study physician for further information.

6. Possible risks and discomfort

2ml of fasting plasma were collected before, 6 and 12 months after administration, totaling 6ml for 3 times.The main adverse reaction of pari calcitol injection used for intervention is hypercalcemia, which will be monitored regularly.

7. Expected benefits

The research doctor will give you sufficient science popularization and education during the research process, which is conducive to your in-depth understanding of the disease. The drug in this study, Paricalcitol, is used for the treatment of secondary hyperparathyroidism, which can alleviate the disease

and may alleviate NGAL related vascular calcification combined with the previous theoretical basis.In addition, the results of this study are expected to provide more clinical evidence for the treatment of vascular calcification in the whole population of uremia patients in the future, which will have scientific, clinical and social benefits.

Viii. Compensation

The clinical information, laboratory examination results and blood samples collected in this study are based on clinically necessary diagnosis and treatment procedures without additional financial or other subsidies. You can withdraw from this study at any time according to your own will during the study period.You should notify your doctor of any discomfort, new changes in your condition, or any unexpected conditions, whether or not related to the study, and he or she will judge and manage them.

Free treatment

The drug paricalcitol observed in this study is a routine clinical medication for secondary parathyroid function in hemodialysis patients. Patients voluntarily use this drug according to the characteristics of their condition and pay for reimbursement according to the original medical insurance on the basis of full communication with doctors. Free treatment is not provided in this study.

X. Compensation

The drugs used in this study are classic drugs commonly used in clinical practice, and the compensation related to health damage should be handled according to the general clinical situation without insurance.

Precautions before, during and after the study

You should immediately notify your study physician of any discomfort, new changes in your condition, or any unexpected conditions, whether or not related to the study, and he or she will judge and manage them.

Xii. Confidentiality

Your privacy will be protected and your personal information will be kept

confidential.Your personal information will not be disclosed unless required by law.Personally identifiable information about you obtained during the study will be (encoded or anonymized), (in what form and where) and will be kept strictly confidential and used only for the purpose of this study.The Research Team will take measures to protect your personal information and will not include any content showing your identity in any research documents, reports or published articles. Research results including laboratory tests and other results will be published for scientific purposes without disclosing your identity.We will do everything within the law to protect the privacy of your personal medical information.

Any records you make in this study will be kept strictly confidential at all times, but the investigator, the study authority, the ethics committee, and the superior inspection department may have access to your medical records and study related information if necessary.When you sign this informed consent form, you consent to the use of your personal and medical information for the purposes described above.

Regain informed consent

According to the requirements of laws and regulations, if the content of this study scheme changes, we will timely communicate with you and re-obtain the informed consent from you to continue.

14. Voluntary

Your participation in this study is entirely voluntary.You may choose to refuse to participate in this study, or at any time for any reason notify the investigator to withdraw from the study, your data will not be included in the study results, and your medical treatment and rights will not be affected.Your decision will not affect your future treatment.If you decide to withdraw from the study, please feel free to inform your study physician.

Xv. Subject obligations

As a subject of this study, you have the following responsibilities:

1. Truthfully provide your medical history and current physical condition;

2. Inform the research physician whether they have participated in other studies and whether they are currently participating in other studies;

3. If you experience any changes in your health condition, any symptoms, or any discomfort, whether or not you think it is relevant to this study, you must promptly inform your study physician.

16. Contact Information

If you have any questions about this study, or if you have any discomfort or injury during the study, please contact Dr. Jia Xiaoyan at 13791135363 or 0531-89269002.

If your personal rights and interests are affected during the study, you can contact the Ethics Committee of the First Affiliated Hospital of Shandong First Medical University (Qianfoshan Hospital of Shandong Province) at 0531-89268212.

Subject signature: Date:

Signature of subject's relative or guardian: date:

Investigator signature: Date: