Informed consent to participate in research projects

Name of clinical research project: Multi-chip Meta-analysis of Parkinson's Disease for Clinical Validation of Small Samples of Key Genes in Disease。

Project undertaking unit: Department of Neurology, Zhujiang Hospital of Southern Medical University

Name of main researcher: Xiaoya Gao, deputy chief physician

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Daytime phone number:

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We now invite you to participate in a study.First of all, you need to understand that participation in this study is entirely voluntary.Secondly, you need to be informed that there is a significant difference between the treatment received in the study and the treatment received by your doctor outside the study:

Outside of research, you and your doctor have a lot of freedom in making decisions about your health.

When you participate in this study, the main purpose is to learn more about the treatment so as to help other patients in the future.The research team (your study doctor and the researchers of the supporting study doctor) will treat you in accordance with the requirements of the study.

So you have to understand the difference between the routine treatment you receive from your doctor and the treatment you receive in the study.

This informed consent provides you with important information about the study.Please read this information carefully before you decide whether to participate in this study.No one can force you to participate, and you can stop participating in the study at any time.If you choose to participate in the study, you need to sign this informed consent form.You will also receive a copy of the signed document for retention.

The following is a description of the study.Please consult your research team, family and friends or other medical professionals to decide whether to participate in this study.The research team will answer any questions you ask before you make a decision.

1. What is the purpose of this study?

1.1 Disease burden and treatment status: Parkinson's disease (PD) is a relatively common degenerative disease of the central nervous system. As society gradually becomes aging, the number of PD patients is increasing, but its exact pathogenesis is still not fully understood. May be related to genetic factors, environmental factors, immunological abnormalities, mitochondrial dysfunction and oxidative stress, ageing, apoptosis and other factors; the current genetic diagnosis is in the ascendant, making the understanding of the etiology and pathogenesis of Parkinson's disease more In-depth, provide more basis and means for the pathogenesis and development of Parkinson's disease, but due to the number of individual samples, operational norms and platform differences, different research groups have great differences in the results of gene chip research on Parkinson's mechanism, resulting in the reliability is poo; in order to improve the reliability of Parkinson's disease onset and development gene diagnosis,We will carry out the research of integrating the results of different research groups by meta-analysis to find the key genes of Parkinson's disease, and carry out the clinical verification.

1.2 purpose of this study: The research group uses the statistical method of meta-analysis to integrate the research results of different research groups on Parkinson's disease chip together, uses meta-analysis to find the key genes related to the pathogenesis and development of Parkinson's disease, and carries out small sample verification in clinical, excavates the internal mechanism of Parkinson's disease and provides guidance and reference for the follow-up experimental research.

1.3 number of study participants and patients included:In the Department of Neurology, Zhujiang Hospital of Southern Medical University, the

patients were divided into PD group, Parkinson-plus syndrome(PPS) group and healthy control group, at least 80, 23 and 110 cases respectively.

2. Who will be invited to participate in the study?

People who meet the following criteria will be invited to participate in the study:

Inclusion criteria:1.PD group: patients with Parkinson's disease were diagnosed according to 2015 International Association of Parkinson's and Movement Disorders Association (MDS);2.PPS group: patients with Parkinson-plus syndrome were diagnosed according to 2017 MDS progressive supranuclear paralysis and 2017 clinical diagnostic criteria for MDS progressive supra palsy and Giman standard, the 2008 American board of neurology (AAN) MSA diagnostic consensus. 3. Healthy controls;

Exclusion criteria: 1.Other causes of Parkinson's syndrome, including cerebrovascular disease, encephalopathy, trauma and drugs; 2.people with ther neurodegenerative diseases, such as huntington's disease, lewy body dementia, alzheimer's disease, etc.3.The person have other disabilities or diseases, such as aphasia, severe dementia or consciousness disorders, malignant tumors, liver and kidney dysfunction, serious heart disease or other acute or chronic diseases or life-threatening diseases. 4.someone who refuse to participate in the study.

3. How many subjects will be recruited in this study?

The study will recruit at least 80 PD patients, 23 PPS patients and 110 healthy controls.The study will be conducted in Zhujiang Hospital of Southern Medical University.

4. How long will the study last?

The standard research phase is about 2 years.

5. What might happen before the study starts?

If you decide to participate in the study, we will ask you to sign this informed consent before any action related to the study.

6. What will happen during the study?

Screening visit

The study will start with screening visits.The purpose of the screening visit is to verify that you meet all the criteria for participation in the study.

If you meet the conditions of the study and choose to participate in the study, you will start the study treatment.

Research procedure

This is a prospective clinical controlled validation study of multi chip meta-analysis is of Parkinson's disease to find key genes of PD, that is, you will be divided into PD group, PPS group or control group according to clinical diagnosis.

In this study, you will receive the following examinations and procedures: the patient's clinical statistical data include age, gender, admission diagnosis, comorbidity, brain CT or MRI examination; at the same time, after the definite diagnosis, 12 ml of three venous blood samples wwill be taken for gene detection , transcriptome chip, protein detection, etc. and then take 20ml of saliva samples for protein detection. And in PD group, MDS-UPDRS, NMSS, HAMD, HAMA, MoCA, PSQI, HOEHN&YAHR (H-Y) grading were used to assess the motor and non motor symptoms and disease severity of PD patients, PSPRS were used to assess the clinical symptoms of PSP patients, UMSARS was used to assess the clinical symptoms of MSA patients.

Treatment phase procedure:

This study is a clinical control verification, does not involve clinical treatment intervention and other means, does not affect the clinical routine treatment of patients, but in order to obtain the real patient information, the family members and patients need to provide the real relevant information.

7. What risks and discomfort may occur in the study?

There are certain risks in any research. Although our research does not involve drugs, surgery and other clinical interventions, it may cause

your discomfort or inconvenience when collecting information and evaluating the Unified Parkinson’s rating scale.We will pay close attention to your discomfort and may take some appeasement measures to relieve it.

If you participate in this study, the most likely discomfort and inconvenience for you are as follows:

1) personal privacy may be involved in the process of information collection, and we will actively exchange and ensure that relevant information is only used as a clinical research institute and not used for other purposes; 2) there may be pain in the process of venous blood collection, we will arrange experienced nurses and strictly follow the relevant process standards to ensure that the discomfort during blood collection is reduced; 3) Parkinson’s patients are conducting relevant scale evaluation,there may be physical or mental discomfort.

8. Apart from participating in this study, what other options do you have?

Your research doctor will discuss with you the standard diagnosis and treatment plan and the development of the disease.You may also choose not to participate in this study.

9. What are the potential benefits of participating in this study?

We will give feedback and discuss the results of your gene test and clinical evaluation with your competent physician, which may be beneficial to your diagnosis and treatment, but we do not guarantee your benefits in any way.The information from this study may help other patients in the future.

10. What should I do if I am harmed by my participation in the study?

If you have research related damage, the research institution will provide or arrange free treatment for you.The cost of the treatment will be borne by the Research Institute.Study related injury refers to the physical injury or disease caused by participating in the study.If you are harmed by a treatment or procedure that you will receive even if you

do not participate in the study, it is not the study related damage. Compensation for mental loss such as lost time, expenses other than medical care or pain is not included. To avoid damage, it is important that you follow all research guidance. In the unlikely event of damage or death caused by the research procedure, the research institution will make medical compensation for the damage and / or other reasonable compensation according to the local laws and regulations of China. By signing this informed consent form, you do not waive any legal rights.

11. Is participation in the study voluntary?

Yes. Whether to participate in the study depends on your decision. You can choose not to participate or change your mind and quit the study later. You will not be punished or lose any rights you are currently enjoying or entitled to enjoy.

If we get some new information that may change your willingness to participate in the study, we will inform you in time. If you decide to quit, please inform us. We will ensure that you terminate the study in the safest way possibly. If necessary, we will discuss the follow-up with you.

The research doctor may withdraw you from the study without your consent if:

You do not follow the guidance of the research team;

In the opinion of the study doctor, this study is not in your best interest;

The study was terminated by a research institution, an independent medical ethics committee (a group of people who review the study to protect your rights), or a regulatory body.

If you withdraw from the study for any reason, the study doctor will ask you to undergo the tests listed in Section 6 for your safety. The study doctor may ask if you would like to participate in the follow-up of the study. If you agree to continue to participate in the follow-up of the study, your health information will be collected as described in Section 6. The

study doctor will discuss with you the different options for quitting the study.

If you withdraw or are withdrawn from the study, records that identify you will remain confidential and will not be made public to the extent permitted by applicable laws and / or regulations. If the results of this study are published, your identity information will be kept confidential,

12. If I participated in this research, what should I pay?

It will take some time to cooperate with the clinical evaluation of the research physician and take 12ml of three venous blood samples and 20ml of saliva samples.

13. Will you be paid to participate in the study?

You will not be paid to participate in this study, but you can get free consultation from the research physician about the latest progress of disease prevention and treatment and answers to related questions.

14. If I participated in the study, how would my personal information be protected?

For the purpose of verification of clinical trial procedures and / or data, the research monitor will have the direct authority to view your original medical records, and will not violate your confidentiality rights to the extent permitted by applicable laws and regulations. By signing this informed consent, you or your legal representative will authorize the above-mentioned personnel to view your original medical records.

The study will keep records that identify you confidential and will not public to the extent permitted by applicable laws or regulations. If the results of this study are published, your identity information will remain confidential.

15. If there are still questions about how to protect rights or other issues, who should I contact?

Before you sign this document, you can ask any questions you don't understand. Your questions will be answered by the research team during

and after the study. If you think the answer is inadequate or incomprehensible, please continue to ask questions until you get a satisfactory answer.

If you have any questions or complaints about the study or how it was conducted, please discuss your concerns with the research team in a timely manner. The telephone number of the research team is shown on page 1 of this article. If you find it inconvenient to discuss your complaint with the research team, please contact the ethics committee listed below.

This study has been submitted to and approved by the ethics committee. If you have any questions about your rights as a study participant, or need to obtain and provide information, or want to talk with relevant people who are not directly involved in the study, please contact: Ethics Committee of Zhujiang Hospital of Southern Medical University.

Address: No. 253, middle of Industrial Avenue, Guangzhou

Tel: 020-62783254

16. signature:

I have been informed of the information about this study and have had the first discussion with the study doctor or research team about the information on the date:_____ and time:_____ (if necessary) (only when the information was provided and the consent was signed on the same day, the time should be indicated). I have read and understood the information in this informed consent, I have the opportunity to ask questions, and all my questions have been satisfactorily answered,

I agree to participate in this study and understand that participation in this clinical study is voluntary, and I can refuse or withdraw from this study at any time without any penalty or damage to my due interests. Signing this informed consent does not mean that I give up any legal rights.

I understand that I will receive a copy of the informed consent signed by name and date.

Name of study participants in block letters

Study participant signature:_____ Date:_____ Time:_____

Name of legal representative and relationship with investigator

Signature of legal representative:_____

Date:_____ Time:_____

People who get informed consent:

Name of the person who conducted the informed consent discussion:

The person who conducted the informed consent discussion Signature:_____

Date:_____ Time:_____

Informed consent of study participants who could not read

Study participants have shown that they are unable to read.The research team will discuss with them to appoint a neutral witness, who will read this document for them, discuss with research participants and neutral witnesses, and give them the opportunity to ask questions.

Name of neutral witness in **regular script:**

Signature of neutral witness:_____

Date:_____ Time:_____

Notes:

[*]Only when the information is provided and informed consent is signed on the same day, or informed consent is signed and any research related action occurs on the same day, the time shall be indicated.

[I]The investigator or appropriately qualified and trained personnel assigned by the investigator must sign the name and date of the form together with the patient during the signing of the informed consent.

[II]Neutral witness: this person is independent of this study and cannot be affected by the injustice of the research related personnel. If the patient or the legal representative of the patient cannot read, the above neutral witness will participate in the informed consent process and read the informed consent and any other written information provided to the patient.