Based on the discussion of electroacupuncture treatment of optic neuromyelitis genealogy diseases (**NMOSD**) Patient

Research project on the curative effect of pain and its mechanism of action

Informed consent form · Informed notice page (research introduction)

Information Leaflet for Informed Consent

Dear Patient,

Your doctor has confirmed that you have optic neuromyelitis.

We will invite you to participate in a discussion on electroacupuncture for the treatment of optic neuromyelitis spectrum diseases (NMOSD) Research on the curative effect of patient pain and its mechanism of action. This study is a randomized controlled clinical study, which will collectfMRIImages, blood samples,Tongue coating samples and fecal samples are used to clarify the intervention effect of electricity on pain in patients with optic neuromyelitis spectrum diseases.

Before you decide whether to participate in this study, please read the following carefully as much as possible, which can help you understand why the study is to be conducted, the procedures and duration of the study, and the benefits, risks and discomforts that may be brought to you after participating in the study. If you want, you can ask your doctor for an explanation, or you can discuss it with your family and friends to help you make a decision.

Research introduction

I. Research background and research purpose

Pain is a spectrum disease of optic neuromyelitis (NMOSDA common symptom of the patient. Known up to86%TaxiNMOSD Patients will be affected by pain. A survey of the quality of life and medical experience of Chinese patients showed that pain is the third problem that patients want to pay attention to in addition to recurrence and drug side effects, and even more plagues the lives of patients than disability. Weigh10% The patient believes that the severe pain caused by the disease greatly interferes with normal life. 6%Patients believe that physical pain seriously hinders them from enjoying life.

NMOSDThe pain of patients is mainly divided into neuropathic pain and spasm-related pain. Some clinical observations suggest clinical factors.(Such as myelitis and emotions)And demographic factors(Such as age)Give NMOSD The

patient's pain is related. At present NMOSD Possible mechanisms of pain andAQP4Deficit, reactive astrocyte hyperplasia and its related inflammatory reactions and abnormal brain structure.

At present, although there are a variety of analgesics and multiple drug combinations for different pain mechanisms, there are still 60-80%TaxiNMOSDPatients with moderate and severe pain and completely get rid of the pain10%. At the same time, there have been a number of large samples and multi-center randomized controlled studies that suggest that electroacupuncture is effective in treating pain. National Institutes of Health (National Institutes Of Health)It is estimated that it exceeds1500Tens of Americans used acupuncture therapy. The use of electric needles is now recognized by the World Health Organization.Among them, the design of fake acupuncture mainly refers to the same type of disease partners published in international journals.Study of painful acupuncture.

According to the comprehensive literature, the research on electroacupuncture treatment of pain has made some progress, which can play an analgesic role by regulating inflammatory factors, releasing analgesic-related factors, and regulating the activity of the corresponding brain area.

Therefore, this study hopes to start from the aspect of electroacupuncture analgesia, by comparing the curative effect of the electroacupuncture group and the false acupuncture group, and then verify the curative effect of electroacupuncture in the treatment of pain in patients with optic neuromyelitis spectrum diseases and its related mechanisms for reference for

This study is a prospective, randomized and controlled clinical trial.NMOSDThe curative effect of patient pain and its mechanism of action. It will meet the layout standards. NMOSD Patients with pain are randomly divided into electroacupuncture groups and false needles using the random method of random number tables.In the group, each group of patients is on the basis of immunotherapy and analgesic treatment.Add electric needles or fake needles for continuous treatment.30God, in order to observe electricity forNMOSDThe intervention effect of pain patients.

This study is led by Guangdong Provincial Hospital of Traditional Chinese Medicine in Guangdong Provincial Hospital of Traditional Chinese Medicine.Dade Road DistrictThe first department of neurology is conducted for research, and it is expected that there will be 20 The subjects volunteered to participate. The Ethics Committee of Guangdong Provincial Hospital of Traditional Chinese Medicine has considered that the study follows the principles of the Helsinki Declaration and is in line with medical ethics.

II. Who is suitable to participate in the research?Incorporation of standards:

1Meet the diagnostic criteria for optic neuromyelitis spectrum diseases;

2Quantitative Table of Digital Rating (NRS) ≥4Points;
3Patients use a stable dose of biological therapy and/Or prednisone, before joining the group30There is no adjustment plan within the day;
4Before the patient enters the group30No standard combination of drugs for pain was adjusted during the day, including antiepileptic drugs, antidepressants and opioids.
5The patient or the patient's family signs an informed consent.
618-80 Old patient.

Exclusion criteria:
1Patients participating in other clinical studies;
2Patients with low cognitive or mental ability.
3People who are pregnant, breastfeeding or planning to get pregnant during the study period;
4People with serious diseases related to the heart, liver, kidneys or the hematopoietic system.
5Patients with diabetic peripheral neuropathy.

III. What do you need to do if you participate in the research?

1.Before you are selected for the study, you will undergo the following checks to determine whether you can participate in the study.

We will ask about your medical history and review all the medicines you are currently taking. You will receive a comprehensive physical examination and perform blood routine, liver function, biochemistry, etc.

2If you pass the above inspection, you will follow the following steps to study.

First of all, you need to fill in detailed demographic data, improve physical examination and detailed neurological examination, and collect blood samples for interleukin. 6 （ IL6), tumor necrosis factor (TNF-Ａ), blood routine, blood biochemistry, liver function and other tests, and take blood samples, tongue coating samples and fecal samples at the same time. This process probably costs you. 30 A few minutes to arrive 60 Minutes and time.

The first treatment (in the group) 1 Day), we will randomly assign you to the electroacupuncture group or the false needle group. The electroacupuncture group will use electroacupuncture treatment on the basis of immunotherapy and basic analgesia treatment, and the control group will receive false needle treatment on the basis of immunotherapy and basic analgesia treatment. Every week 2 Time, every time 30 Minute electric needle (true or false), continuous 1 Months, a total of 8 (The course of treatment is 30 God). Patients fill in the pain diary every day, and the treatment is carried out by the same acupuncture doctor. The manufacturer and use method of acupuncture, false acupuncture and electroacupuncture instruments are consistent. The process will probably cost you. 30 A few minutes to arrive 60 Minutes and time.

Visit after the eighth treatment (in the group) 28±3 Day): The nurse will collect your blood for blood routine, biochemical and liver function tests. Improve the extended disability status scale score (EDSS), digital rating scale (NRS), McGill's pain questionnaire (McGill pain questionnaire, MPQ)Quality of Life Scale (SF-36), anxiety self-assessment scale
（SAS), depression self-assessment scale (SDS), improve functional nuclear magnetic resonance (fMRI) Check and collect relevant data, and keep blood samples, tongue coating samples and fecal samples. The process will probably cost you. 60 A few minutes to arrive 120 Minutes and time.

This study will keep your blood samples, tongue coating samples and fecal samples for discussion. NMOSD The relevant mechanism of pain in patients and the mechanism of electroacupuncture treatment of pain in patients with optic neuromyelitis spectrum diseases. All samples will be frozen in the Biological Resource Center of Guangdong Provincial Hospital of Traditional Chinese Medicine for preservation. 3 Years, and the samples were destroyed after the end of the research. All samples are only used for this study, and your personal information will not be disclosed. Researchers, personnel of the Biological Resources Center and the Ethics Committee will be allowed access to these samples, and you can request to withdraw from the sample retention or research at any time.

3. Other matters that need your cooperation

You can't use other pain-related research drugs at will during the study.

4. The expectation that your participation in the trial may be terminated and/Or the reason

During the research process, you can withdraw from the research at any time for any reason, or the researcher believes thatYou should stop the study.

IV. Possible benefits of participating in the research

This study is expected to improve NMOSD Provide new ideas for the treatment of patients' pain, for NMOSD Provide more effective strategies for combining traditional Chinese and Western medicine to reduce the social burden. You and the society may benefit from this study. Such benefits include your symptoms and the possibility of improvement in your condition. If you choose this plan, you will have a good chance to get a good prognosis. At the same time, the subjects participating in the study will receive stricter regular follow-up and clinical guidance. During the research process, the research doctor will pay close attention to your physical condition and evaluate it in time. Your participation may be helpful to you and future patients.

V. Possible adverse reactions, risks, discomforts and inconveniences of participating in the study

All treatments may have side effects. After using this treatment method, there are occasional adverse reactions such as dizziness needles, hematomas,

stagnant needles, etc., all of which are mild and have no obvious discomfort. After a short-term review, it will return to normal. During the treatment, the medical staff will closely observe and take timely, reasonable and necessary treatment measures for any adverse reactions. Patients with mild hematoma can use a disinfectant cotton swab or cotton ball for local compression to stop the bleeding without special treatment. Patients with moderate and severe hematoma should take corresponding measures according to the degree of hematoma, first stop bleeding to prevent local swelling from increasing, carry out local anti-inflammatory treatment, and ask a surgeon to assist in treatment.

If you have any discomfort in the study, or new changes in your condition, or any unexpected situation, whether or notThe treatment method should be notified to your doctor in time./She will make a judgment and medical treatment on this. Doctors will do their best to prevent and treat the damage that may be caused by this study. During the study, if you have an adverse event, your doctor will determine whether it is a damage related to the trial. Indeed, because the test causes harm to you, you can get timely and effective treatment in your hospital.

During the research period, you need to go to the hospital on time for follow-up, do some physical and chemical examinations and keep tongue coating specimens, which may cause trouble or inconvenience to you. There may be slight discomfort when collecting blood samples. Side effects that may be caused by blood sampling include dizziness, venous inflammation, pain, bruises, or bleeding at the puncture site, and there is also a small possibility of infection. In addition, any treatment may occur.Ineffective situations, and the condition continues to develop due to ineffective treatment or other diseases. This is the treatment risk that every patient will face. Even if you do not participate in this clinical study, the treatment risk will exist. During the study, if the doctor finds that the treatment measures taken by the study are ineffective, the study will be terminated and other possible effective treatment measures will be used instead.

Ⅵ. Related expenses

The topic will pay you to participate in acupuncture treatment during this study.fMRIThe cost of examination required for other clinical routine diagnosis and treatment shall be borne by yourself (Due to the high recurrence of the disease and the use of immunosuppressants, blood routine, biochemical, liver function, IL6、TNF-Ａ, MRI scanning is a relevant inspection that requires routine review). This study does not add you.The cost.

In case of damage related to the test, the research group will pay your medical expenses and give you corresponding economic compensation in accordance with laws and regulations.

If you combine the treatment and examination required for other diseases at the same time, it will not be included in the free range.

7. Is personal information confidential?

Your medical records (research medical records)/CRF, test sheet, etc.) will be kept intact in the hospital, and the doctor will record the test results on your outpatient medical record. Researchers and ethics committees will be allowed to access your medical records. Any public report on the results of this study will not disclose your personal identity. We will do it to the extent permitted by law. Make every effort to protect the privacy of your personal medical information.

This study will keep your blood samples, tongue coating samples and fecal samples for discussion. NMOSD Research on the mechanism of pain in patients and the mechanism of electroacupuncture on the pain of patients with optic neuromyelitis spectrum diseases. All samples will be frozen in the Biological Resource Center of Guangdong Provincial Hospital of Traditional Chinese Medicine for preservation.3 Years, and the samples were destroyed after the end of the research. All samples are only used for this study, and your personal information will not be disclosed. Researchers, personnel of the Biological Resources Center and the Ethics Committee will be allowed access to these samples, and you can request to withdraw from the sample retention or research at any time.

8. How to get more information?

You can ask any questions about this study at any time. Your doctor or researcher will leave him for you./Her phone number so that she can answer your questions.

If you have any complaints about participating in the research, please contact the Office of the Ethics Committee of Guangdong Provincial Hospital of Traditional Chinese Medicine (Tel: 020-81887233-35943)。

If there is any important new information in the course of the research, which may affect your willingness to continue to participate in the research, your doctor will inform you in time.

IX. You can voluntarily choose to participate in the research and withdraw from the research halfway.

Whether to participate in the research depends entirely on your willingness. You can refuse to participate in this study or withdraw from it at any time in the research process, which will not affect your relationship with your doctor, nor will it affect your medical treatment.There is a loss of other benefits.

Your doctor or researcher may terminate your participation in this study at any time for your best interests. If you do not participate in this study, or withdraw from the study halfway, there are many other alternative treatments, such as traditional treatments. You don't have to choose to participate in this

study to treat your illness. If you withdraw from the study for any reason, you may be asked about your use of the experimental method. If the doctor thinks it is necessary, you may be required to have a laboratory examination and a physical examination, which is very beneficial to protect your health.

X. What should I do now?

Before you make a decision to participate in the study, please ask your doctor as many questions as possible until you fully understand the study.

Whether to participate in this study or notIt's up to you. You can discuss it with your family or friends before making a decision.

Thank you for reading the above materials. If you decide to participate in this research, please tell your doctor or research assistant, who will arrange all the research-related matters for you.

Please keep this information.

Informed consent form · Agree to the signature page

Signature Leaflet for Informed Consent Project Name:

Discussion on Electroacupuncture TherapyNMOSDResearch applicant on the curative effect of patient pain and its mechanism of action/Project agency: Guangdong Provincial Hospital of Traditional Chinese Medicine

Ethical review approval number: Ethics Committee of Guangdong Provincial Hospital of Traditional Chinese Medicine

Statement of consent

I have read the introduction of the above-mentioned research and have the opportunity to discuss and ask questions with doctors about this research. All the questions I asked were answered satisfactorily.

I know the risks and benefits that may arise from participating in this study. I know that participating in the research is voluntary, and I confirm that there is enough time to consider it, and I understand that:

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

I also know that if I withdraw from this study halfway, especially when acupuncture treatment makes me withdraw from the study, if I tell the doctor about the change of the condition and complete the corresponding physical examination and physical and chemical examination, it will be very beneficial to me and the whole research.

If I need it because of illnessIf I take any other medication, I will consult the doctor in advance or tell the doctor truthfully afterwards.

I agree that the drug control department, the ethics committee or the applicant's representative can consult my research materials.

I will get a signed and dated copy of the informed consent form.

Finally, I decided to agree to participate in this study.

Subjects Signature:_____Date: _____Year____Moon___Sun Contact number:

Guardian/Authorized client Signature:_____ Relationship with subjects:

(Note: The subjects did not/If the informed consent cannot be signed for reasons such as limited capacity to conduct, it shall be signed by the guardian or authorized principal)

Contact number:_____Date:_____Year____Moon____Sun

I agree.☐ Or refuse☐ Other studies other than this study use my medical records and biological specimens.

Subjects Signature:_____ Date: _____Year Moon_____Sun

Guardian/Authorized client Signature:_____ Relationship with subjects: Date:_____Year___Moon___Sun
(Note: If the subject is unable to sign the informed consent due to incapacity and other reasons, it shall be signed by his guardian or authorized principal)

I confirmed that I had explained the details of this trial to the subjects, including their rights and possible benefits and risks, and gave them a signed copy of the informed consent form.

Researcher Signature:_____ Date: _____Year_____Moon Sun

Researcher's work phone number:_____ Mobile phone number:
Contact number of the Office of the Ethics Committee of Guangdong Provincial Hospital of Traditional Chinese Medicine:020-81887233-35943