ID: 2018ZY008-CTN

Research name:

Electroacupuncture Therapy for Change of Pain in Classical Trigeminal Neuralgia

Date: June 20, 2018

Informed consent • Informed page

Dear patients:

We will invite you to participate in a clinical research of the different efficacy of electroacupuncture (EA) and drug in the treatment of trigeminal neuralgia (TN). The study which is the program for Tacking Key Problems of disease prevention and treatment in Zhejiang Province, is intending to treat TN by efficiently clinical methods, and evaluate the effect of TN with EA by comparison of efficacy and safety scientifically. Please read the following words carefully, which will help you understand the details of the study. If you wish, you can discuss it with your relatives and friends, or ask your doctor to give an explanation to help you make a decision.

1. Research introduction

TN is a common neurological pain disease, which is defined by the International Pain Association as a pain occurred in trigeminal nerve distribution area usually one-sided, suddenly, seriously, shortly, knife-like sharp. This is a paroxysmal pain and pain onset time lasts for a few seconds to several minutes. The attack is often without periodicity and intermittent period can be asymptomatic. The pain will be caused by chewing, swallowing, brushing, touching and other face-related movements. The morbidity of the disease has been increasing in recent years, which attacked women more than men and the age of onset can be

at any age stage, while patients in 40-60 years old is much common. For the treatment of TN, carbamazepine and surgery therapy have been commonly used. Although both of them have explicit effect, but they usually have the characteristics of high cost, great minus effects and high-rate of relapse. Due to the above situation, it is necessary to find out an effective and inexpensive treatment to alleviate pain of TN. EA, a therapy of acupuncture with electronic stimulation, is widely applied in clinical for TN. But the scientific clinical research was lacking. In order to further clarify the efficacy of EA therapy in the treatment of TN, the clinical research will be operated by the Third Affiliated Hospital of Zhejiang Chinese Medical University with Jiaxing TCM hospital.

2. Who is unfit to participate in the study?

(1) Those patients with epilepsy, head injury or other related neurological diseases.

(2) Patients with serious heart, liver, kidney damage or cognitive impairment, aphasia, mental disorders, or unable to cooperate with the treatment.

(3) Combined with hypertension but poor control.

(4) Severe depressive with definitive diagnosis recently.

(5) Pregnant and lactating patients.

(6) Installing pacemakers.

(7) For any other reason that is not suitable for the treatment of EA.

3. What would you do if you took part in the study?

3.1 You will receive the following checks to determine whether you can participate in the study:

The doctor will inquire and record your medical history, make a physical examination. Some people will receive a CT check to make the diagnosis clearly.

3.2 If you meet the inclusion criteria and be ready to participate in this study, the following steps will be taken:

(1) You will be distributed to the EA group or the drug group according to the random numbers provided by random system. . The subjects of drug group were orally took the carbamazepine, which is a classical medicine in clinical.

(2) The treatment period of this project is 4 weeks, and the follow-up period is 6 months. The evaluation time points are baseline measurements (the same day with the randomized grouping and first day of treatment if a subject was grouped in the same day), treatment period assessment I (end of 2nd week), treatment period evaluation II (end of week 4th), follow-up evaluation I (3rd months after the end of treatment), follow-up evaluation II (6th months after the end of treatment) are evaluated accordingly. The treatment period of EA group is 4 weeks with 3 times a week, a total of 12 times.

(3) You need to cooperate with the doctor in the appropriate time to do

therapeutic effect evaluation, please truthfully feedback your treatment changes during the study.

3.3 Other matters required your cooperation

As participant in this study, a number of responsibilities need you to do. Such as you have to receive the treatment and examination on time and cooperate with us completing for outpatient in the follow-up period. If you have any changes about your physical or mental health, you'd better report to doctor in time regardless of whether the changes to be relevant to the study you considered.

Other acesodyne are not allowed taking during the trial. However, if pain is continuing and can't be alleviate, even some serious influence is impacting on your daily life, the carbamazepine 0.2gcan be emergency used (or added), once time a day after meal. The time and dosage of emergency medications or other analgesic measures must be recorded timely.

Please follow the study's schedule to receive the outpatient (during the follow-up period, the doctor may contact you by telephone). Your doctor will determine if the treatment is really working and guide you in the prevention and control of the disease by your outpatient.

4. The benefit of participation in the study

The treatment of EA or drug in total of 4 weeks will provide to you for free. And you will receive a series of related medical services,

including examination, treatment and answer your medical questions.

5. Adverse reactions, risks, discomfort and inconvenience that may occur in the study

Doctors will do their utmost to prevent and treat the possible harm caused by this study.

During the acupuncture, you may feel acid, numbed, heavily, distensible which are the normal reaction of acupuncture. Acupuncture may have adverse reactions, but the side effects are rare. Acupuncture syncope reaction may be caused by your physical problems or emotional tension, which can be alleviated by stopping acupuncture and proper rest. After acupuncture, there may be bleeding, hematoma and other phenomena, which can be disappeared after pressure. If there is an infection at the acupuncture point, your doctor will handle it promptly.

Very few patients may have gastrointestinal discomfort, dizziness, heart palpitations, liver toxicity or other side effects by taking carbamazepine. When reducing the dose or withdrawal, it can be returned to normal. So it doesn’t need to interrupt treatment.

According to the research plan, if there is any adverse reactions and events during the treatment, please call the doctor at any time for assistance. The doctor will give a positive and reasonable treatment for you.

6. **Related expenses**

If you take part in this study, the treatment fee and drug charge are free. If an adverse event occurs in the study, the medical expert committee will identify whether it is related to the trial process. If there is any damage related to the trial, the research group will pay your medical expenses. The treatment and inspection required for the other diseases that you combine together will not be within the free range.

7. **Is personal information confidential ?**

All information you have entered into this study will be kept confidential and kept by the subject unit in charge and your research unit. Only the unit responsible for the study, clinical trial research units and ethics committees will have direct chance to access to your case record. Your name will not appear in any published information or report on this study.

We will make every effort to protect the privacy of your personal medical information within the scope of the law.

8. How to obtain more information ?

You can submit any questions about this study at any time and get the corresponding answers.

Your doctor will inform you promptly of any important new information that may affect your willingness to continue participating in the study during the study.

9. **Can I volunteer to participate in the study and withdraw from the study?**

Whether to participate in the study depends on your own wishes entirely. You may refuse to participate in this study or withdraw from this study during the research process, which will not affect the relationship between you and your doctor, and will not affect your medical treatment and rights.

For your best interest consideration, a physician or researcher may suspend your participation in the study at any time during the study.

If you withdraw from the study for any reason, you may be asked relevant circumstances relating to your use of acupuncture or drug treatment. If the doctor thinks it is necessary, you may also be required to carry out a laboratory examination and physical examination.

10. **What should I do now?**

Whether to participate in this study is decided by yourself (and your family).

Please ask your doctor about the study as much as possible before you make a decision to participate in the study.

Thank you for reading the above materials. If you decide to take part in this study, please tell your doctor that he/she will arrange the follow-up matters for you.

Please keep this information.

Informed consent • Agree signed page

Consent statement

I have read the research materials carefully and ask questions about the study with the doctor. All my questions have been answered satisfactorily. I have understanded the information on medical research, the possible risks and benefits of the study. I confirm that I have plenty of time to consider and knowing that participation in the study is voluntary. I understand:

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

I agree that the sponsor, clinical trial research units and ethics committee have right to review my research materials.

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

Finally, I decided to agree to participate in this study and pledged to follow my doctor's advice.

Patient's signature: Date：

Contact number:

Doctor's statement

I confirm that the details of the trial have been explained to the patient, including its right, possible benefits and risks. A copy of the informed consent has been signed to the patient.

Researcher's signature: Date：

Contact number: