Institutional Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine

Information Leaflet for Informed Consent

Dear patients,

Your doctor has confirmed that you are suffering from stroke (including cerebral infarction and cerebral hemorrhage) .

We will invite you to participate in a clinical research named Using fMRI and sEMG to Evaluate the Effects and Mechanism on Abdominal Acupuncture Combined With Upper Limb Rehabilitation Training on Brain Plasticity of Hemiplegic Patients With Stroke.

Before you decide whether to participate in this study, please read the following materials carefully as much as possible to help you understand the research and why you should conduct this research, including the procedures and deadlines of the study, and the benefits that may be brought to you after participating in the study , risk and discomfort. If you prefer, 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

1. Background and Purpose

Cerebral infarction is the main type of stroke which has become hotspot and difficulty of the research in medical science because of its high morbidity, disability and mortality. Stroke has caused great harm and burden to patients' family and society. It was reported by WHO that 80% of stroke patients have different degrees of limb dysfunction. With the intervention of rehabilitation therapy, some patients would recover in different degrees within 6 months. However, more than 60% of patients still remain upper limb dysfunction in chronic phase. According to the literature, only 15% of patients with stroke can recover to 50% of the original hand function. Only 3% of them can recover to more than 70% of the original. Because the motor function recovery of upper limb and hand is more difficult than that of lower limb. So we often pay more attention to the motor function recovery of lower limb and ignore the motor function rebuilding of upper limb. In addition, the disuse of affected hand and compensatory of unaffected hand of stroke patients lead to “learning without practice” and hand muscles contracture. If we start rehabilitation training now, the effects of rehabilitation training will be unpleasant and reduce the activities of daily living and quality of life seriously. Professor Bo, the famous abdominal acupuncture expert , using abdominal acupuncture treated hemiplegic patients with stroke and achieved remarkable effects. The

acupuncture points of abdominal acupuncture form a turtle chart at the abdomen. Zhongwan point is on behalf of head, Shangqu point is on behalf of neck and shoulder joint, Wailing point, Upper rheumatic point and Upper rheumatic external point are on behalf of shoulder in the turtle figture. The affected upper limb motor function can be improved by acupuncturing the Zhongwan, Shang Qu, Wailing, Upper rheumatic and Upper rheumatic external points. Because it can regulate and control the head, shoulder and hemiplegic limb and achieve the "holographic feedback" phenomenon. But the exact mechanism is not yet clear.

Hemiplegic patients with first onset stroke were treated with abdominal acupuncture combined with upper limb rehabilitation training to observe the recovery of upper limb motor function, the muscles synergy monitored by sEMG, local brain area activation by fMRI and the integrity of pyramidal tract of cerebral white matter. We hope to analyze the changes of upper limb motor function the relationship between the changes and sEMG or brain fMRI and to explore the possible mechanism of abdominal acupuncture combined with upper limb rehabilitation training on brain plasticity of upper limb motor function recovery in hemiplegic patients with stroke.

This research is a clinical trail of 3 groups with completely randomized grouping, positively parallel control. If you agree to participate in our research, you will be randomly assigned to one of the 3 groups for treatment (Group A (abdominal acupuncture + upper limb rehabilitation Training), Group B (sham abdominal acupuncture + upper limb rehabilitation Training), Group C (Upper limb rehabilitation Training)).

This research has been approved by Institutional Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine, which has considered that it is in accordance with the principles of the Helsinki Declaration and is in line with medical ethics.

2. Who is suitable to participante in this research?

① First onset stroke, Left hemiplegia, Right-handed， and diagnosed by brain CT or MRI;

② Age 35 to 75 years old;

③ Course of disease 0.5 to 3 months with stable vital signs;

④ No cognitive impairment. Can understand and execute commands. MMSE score more than 7 points. ;

⑤ Can control the sitting balance. Brunnstrom stage of hemiplegic upper limb and hand is Ⅳ or Ⅴ， Fugl-Meyer Motor Assessment score of upper limb 20-50 point;

⑥ Agree to sign the informed consent;

⑦ Unilateral neglect.

3. What will you do if you participate in this research?

① Before you are enrolled in the study, you will receive the following checks to determine whether you can participate in the research.The doctor will ask and record your medical history and make a comprehensive physical examination of you.You need to carry out blood routine, stool routine, urine routine, liver function, kidney functions, electrocardiogram and other physical and chemical examination.

② If you pass the above inspection, you will follow the steps below to conduct research. You will be randomly assigned to one of the 3 groups for treatment, neither your doctor nor you will know the enrollment beforehand. Then you will receive treatments lasting for 4 weeks, and evaluations before ,2 weeks and 4weeks after treatment.

③ Other matters that require your cooperation

You need to visit the hospital according to the time of your oppointment.

If you need other treatments during the study period, please contact to your doctor beforehand.

Requirement about diet and life living: low fat low salt diet, smoking cessation, keeping emotional stability.

④ Expected circumstances and/or reasons for which you may be terminated in the trial

Patients with severe adverse reactions in clinical trial should discontinue the trial.

Patients with serious complications or rapid deterioration of the disease should discontinue the trail.

4. Possible benefits

You and the community will probably benefit from this study.Such benefits may include improvements in your condition, helping develop a new treatment for other patients with similar conditions.

5. Possible adverse reactions, risks and discomfort, inconvenience

All treatments are likely to have side effects. If you have any discomfort in the study, or a new change in your condition, such as a natural stroke, or any unexpected situation, whether or not it is related to the treatment, you should inform your doctor in time, and he/she will make a judgment and medical treatment.

During the treatment, we regularly check your liver and kidney function, coagulation function, blood, urine routine and electrocardiogram. Doctors will do their utmost to prevent and treat the injuries that may result from this study.

In addition, any treatment is likely to be ineffective, as well as the treatment is

ineffective or because of the combination of other diseases and other causes of the disease continuing to develop. This is the treatment risk that every patient will face, and even if they do not participate in this clinical study, the risk of treatment will be present. In the course of the study, if a doctor discovers that the treatment measures taken by this Institute are ineffective, it will terminate the study and switch to other potentially effective treatment measures.

6. About expenses

During the trial treatment, we will provide you with free and regular examination of the surface electromyography, functional MRI and so on. If the damage is related to the test, the subject group will pay for your medical expenses. If serious adverse effects affect inpatient care, the group will also provide appropriate nutrition fees, unpaid wages and compensation for bonuses. If you combine the treatment and examination required for other diseases at the same time, like hypertension, coronary heart disease and other basic disease, the treatment drugs will not be within the free range.

7. Is personal information confidential?

Your medical records (Research records,/CRF, test sheets, etc.) will be kept intact in the hospital, and the doctor will record the results on your outpatient records. Researchers, sponsor representatives 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 make every effort to protect the privacy of your personal medical information within the bounds of the law.

8. How to get more information?

You can raise any questions about this study at any time.Your doctor or researcher will leave his/her phone number on order to answer your question.
If you have any complaints about participating in the study, please contact the Office of the Institutional Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine (tel: 020-81887233-35943).
If there is any important new informations in the research process that may affect your willingness to continue participating in the study, your physician will notify you in time.

9. Voluntarily participation and half way out of the research

Whether you take part in the study depends entirely on your willingness.
You may refuse to participate in this study, or withdraw from this study at any time during the course of the study, which will not affect your relationship with the physician and will not affect any other loss of interest in your medical care.

10.What shall you do now?

Before you make a decision to participate in the study, please ask your doctor about the questions as much as possible until you fully understand the study. It is up to you to decide whether to take part in this study.You can discuss it with your family or friends before making a decision. Thank you for reading the above materials.If you decide to take part in this study, please tell your doctor or research assistant that he/she will arrange all the relevant research matters for you.

Please keep this information!

Signature Leaflet for Informed Consent

Name of clinical research: Using fMRI and sEMG to Evaluate the Effects and Mechanism on Abdominal Acupuncture Combined With Upper Limb Rehabilitation Training on Brain Plasticity of Hemiplegic Patients With Stroke.

Applicant/Subject Issue unit: Guangdong Provincial Hospital of Chinese Medicine

The code of the ethical review: Institutional Ethics Committee of Guangdong Provincial Hospital of Chinese Medicine

Consent statement:

I have read the above introduction to this study, and have the opportunity to discuss and raise questions with the doctor on this study.

All the questions I have raised have been answered with satisfaction. I know the risks and benefits of participating in this study.

I am aware that participation in research is voluntary, and I confirm that there is enough time to consider this and understand the following information:

● I can consult my doctor for more detailed information.

● I can withdraw from this study at any time, without discrimination or retaliation, and medical treatment and entitlements will not be affected.

I am equally aware that if I withdraw from this study, especially as a result of the drug causes me to withdraw from the study, if I tell the doctor about the change of condition, complete the corresponding physical examination and physical and chemical examination, this will be very beneficial to me and the whole study.

If I need to take any other medications as a result of the illness, I will ask the doctor for advice beforehand or tell the doctor truthfully afterwards.

I agree with the drug regulatory authorities, the ethics Committee or the sponsor representative to consult my research materials.

I will receive a copy of the signed and dated pic.

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

Patient/Subject Signature:_____ Date:_____

Guardian/authorized principal Signature:_____ Date:_____

Contact Tel:_____ Mobile phone number:_____

I confirm that the details of this trial have been explained to the patient, including its rights and possible benefits and risks, and a copy of the signed pic.
Doctor' Signature:_____ Date:_____

Doctor's work Tel:_____ Mobile phone number:_____

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