

Research name:

The effect of acupuncture on Hemodialysis patients with restless legs syndrome(RLS)

Principal Investigator(s): Jia-Ming Chen

Institution: CHANGHUA CHRISTIAN HOSPITAL, TAIWAN

Protocol No. : Y_105_0300 / CCH IRB No. : 170217

Date of Approval: Aug 23, 2019

Duration of Approval: from Aug 23, 2019 to Jul 17, 2020

Informed Consent: Ver.8, Jul 26, 2019

Continuing review: The protocol extends for one year

Informed consent · Informed page

Dear patients:

It is our pleasure to invite you to participate in a clinical research entitled 'The effect of acupuncture on dialysis patients with restless legs syndrome(RLS)'.

Please read the following contents 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

Restless legs syndrome (RLS), a common sensorimotor movement disorder first described in detail by Ekbom, ranges in severity from merely causing annoyance in the patient to affecting sleep and quality of life severely enough to warrant medical treatment. Remarkable differences in prevalence rates of RLS can be observed across countries and geographic regions. Epidemiological research demonstrates that the prevalence of RLS in adults (18 years or more) ranges from less than 1% in Singapore to approximately 10% in Europe and the United States. In 1995, a uniform diagnosis of RLS was made possible worldwide, based on the criteria proposed by the International RLS Study Group (IRLSSG). According to the most recently revised diagnostic criteria, the four clinical manifestations mandatory for the diagnosis are:

(1) an urge to move the legs, accompanied or caused by uncomfortable and unpleasant sensations in the legs;

(2) the urge to move or the unpleasant sensations begin or worsen during periods of rest or inactivity;

(3) the urge to move or the unpleasant sensations are partially or totally relieved by movement;

(4) the urge to move or the unpleasant sensations are worse in the evening or night or only occur in the evening or night.

Acupuncture, an ancient Chinese medical therapy used in the prevention and treatment of disease, is another useful method for treating RLS. It involves inserting needles into specific points (acupoints or Xue Wei) on the human body to bring about its therapeutic effects. Conventional science suggests that acupuncture works by neurological, neurohormonal as well as psychological mechanisms, and it is thought to confer an analgesic effect. Several kinds of acupuncture methods, such as body acupuncture, auricular acupuncture, scalp acupuncture, electro-acupuncture, laser acupuncture, acupressure, acupoint injection therapy (injection of drugs into acupoints) or a combination of the approaches mentioned above, are used in the treatment of RLS.

The mechanism of acupuncture treatment for RLS is still ill-defined. According to our preliminary research, the current practice of acupuncture for RLS is mainly based on principles of Traditional Chinese Medicine (TCM) rather than conventional science. The traditional explanation, based on TCM theory, is that acupuncture restores the balance between Yin and Yang and regulates Qi (the essence) and blood so that integral unity can be maintained and miscellaneous diseases cured.

The development of this disorder in hemodialysis patients is progressive, affecting various physical and psychological dimensions over time. The symptoms of this syndrome are greatly intensified at rest, and are relieved by moving the

extremities, especially the legs. In hemodialysis patients, the symptoms mainly occur during dialysis when the patient is at rest and cause discomfort. Evidence suggests that RLS in hemodialysis patients is associated with a risk of cardiovascular disease, osteoporosis, musculoskeletal pain, and increased mortality. In the general population and in patients with end-stage renal disease (ESRD), the potential causes of RLS include anemia, pregnancy, iron deficiency, the dysfunction of dopamine within the central nervous system, a family history of RLS, and peripheral neuropathy. In patients with ESRD, iron deficiency, anemia, and dialysis are predisposing factors that can lead to RLS.

Some clinical trials have examined the efficacy of acupuncture in the treatment of RLS and demonstrated that it was able to alleviate the clinical symptoms. To our knowledge, however, There have been no studies on the impact of acupuncture therapy on RLS in patients undergoing hemodialysis. Therefore, the present study was conducted to determine the effect of acupuncture on the severity of RLS in hemodialysis patients

2. Research objectives

This study aims is that Restless legs syndrome (RLS) is a common disorder in hemodialysis patients. The present study was conducted to determine the effect of acupuncture on the severity of RLS in patients undergoing hemodialysis. The results of this study could provide the efficacy of acupuncture in the treatment of RLS in hemodialysis patients

3. What should I do if I participant in this study?

If you meets the inclusion criteria and agree to participant in the study, you will receive a demographic information questionnaire and the International Restless Legs Syndrome Rating Scale (IRLSRS) and HRV test. You will be asked to stabilize for 15 minutes in a supine position in the experimental room before formal detection. You need to keep silent and normal breath and avoid limb movement during the whole measuring period. Acupuncture is treated for 4 weeks, 2 times per week. Then following a 2-week washout period, patients will be crossed over to either sham or true acupuncture treatment for 4 weeks, 2 times per week.

4. What is the inclusion and exclusion criteria?

4.1 Inclusion criteria

- (1) Dialysis patients with RLS
- (2) The symptoms expressed \geq 3 months and more than twice per week.
- (3) A score of at least 20 corresponding to severe RLS (International Restless Legs Syndrome Rating Scale, IRLSRS).Dialysis patients with RLS
- (4) between the ages of 18 years and 80 years

4.2Exclusion criteria

- (1) Idiopathic RLS
- (2) Other movement disorders, various psychiatric and organic disorders, cognitive impairment, or bleeding disorders, on anticoagulant therapy, or cardiac pacemaker.

5. What are the benefits if I participate in the study?

If you participate in this study, it will possibly make you relieve the uncomfortable symptoms with RLS.

6. What is the risk if I participant in this study?

Acupuncture is generally considered to be safe when done by a trained professional. The most common side effects of acupuncture include bleeding, soreness, or bruising at the site of needle insertion. Other risks of acupuncture include dizziness, fainting, local internal bleeding, convulsions, hepatitis B, dermatitis, nerve damage, increased pain, and very rarely injury to an internal organ. The number of complications reported to the FDA is relatively low, given that millions of people receive acupuncture treatment each year.

7. Will my medical expenses increase if I participate in this study?

No. We do not charge any fees in this study. All examinations on the biological characteristics of meridian phenomenon are free.

8. What is the compensation if I participant in the study ?

We will offer you NTD100 each time as traffic expenses at your each visit.

9. What is the compensation if I suffer from serious adverse events during the study?

If you suffer from any serious adverse events due to this study, the researchers will compensate you according to relevant laws and regulations of Taiwan.

10. Is personal information confidential ?

Your personal information will be kept in the study record and case report forms. All test results (including your personal information, laboratory test report, etc.) will be kept completely confidential. Your name will not appear directly in the case report form or published papers, instead, only the abbreviation of your name and the assigned code will appear.

If necessary, members from the drug administration department, ethics committee, or the funding authority of the study will have access to your research material according to relevant regulations. However, without permission, they don't have the right to use the data of your personal information for other purpose or disclose it to other organizations.

11. How to obtain more information ?

You can submit any questions about this study at any time and consult Dr. Jia-Ming Chen. His mobile number is 86-47238595. During the study, the researchers will inform you of any new information promptly that may affect your willingness to continue participating in the study.

12. Will I be forced to take part in the study?

It is your own right to decide whether you want to participate in the study. You could refuse to participate in this study for any reason.

13. Could I quit the study at anytime during the study?

You have the right to withdraw from this study at any time during the research, which will not affect your rights and you will not be discriminated or retaliated against. If you choose to participate in this study, we hope that you will be able to complete the entire research process.

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

If you withdraw from the study due to any reasons, you may be asked relevant information. If the physician thinks it is necessary, you may also be asked to carry out a laboratory examination and physical examination. You may also refuse the request and you will not be discriminated or retaliated against.

14. What should I do now?

Whether to participate in this study is decided by yourself. You can also discuss it with your family or friends before making a final decision. Before you make your decision, please ask your doctor about more details so that you could completely understand the study.

15. How to contact the ethics committee?

If you have any problems or complaints during the study, please contact the Institutional Review Board Committee A Changhua Christian Hospital, Taiwan.

Address: 135 Nanxiao St., Changhua City, Changhua County 500, Taiwan (R.O.C.)

Tel: 886-4-723-8595

Officers: ShihLi Su, Ph.D

Thank you for reading the informed consent form. If you decide to participate in this study, please tell the researchers, they will arrange all the matters for you. Please keep this informed consent form by yourself.

Informed consent · Signature page

Patient's statement

1. I have read this informed consent form, and the doctor has explained the purpose, contents, risks and benefits of this experiment to me in details.
2. I have discussed and asked relevant questions about this study and I am satisfied with the answers.
3. Plenty of time is offered to me for making a decision on whether I should participate in this study.
4. I participate in this clinical study on my own decision.
5. If I withdraw from the trial due to the reasons related to the study, I will inform the doctors of the change of my health condition in time.
6. If I receive any additional treatments due to the change of my health condition, I will seek for the doctor's advice in advance or tell the doctors afterwards.
7. I allow members from the drug administration department, ethics committee, or the funding authority of the study to have access to my research materials.
8. I will receive a copy of the signed informed consent with the date written on it. Finally, I have decided to participate in this study.

Patient' signature:

Date :

Contact number:

Doctor's statement

I confirm that the details of the trial have been explained to the patients, 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: