Version: 2.0 Date: 2021/5/30

Taoyuan General Hospital, Ministry of Health and Welfare, Taiwan.

Informed Consent Form (ICF)

Protocol Title:
The Evaluation of Treatment of Leprosy Wounds With Traditional Chinese Herbal Medicine Complex "Jingchuang Ointment"

Trial Institution: Lo-Sheng Sanatorium, Ministry of Health and Welfare, Taiwan.

- Principal Investigator: Dr. Hsu Wei-Hung.
  Title: Director of Chinese Medicine, Lo-Sheng Sanatorium, Ministry of Health and Welfare, Taiwan.
- Sub-Investigator: Lin Tung-Yi.
  Title: Assistant professor at Institute of Traditional Medicine, School of Medicine, National Yang-Ming University

24-hour emergency contact person: Dr. Hsu Wei-Hung. 09**-***-***

1. Abstract：

During the Leprosy onset, the disease mainly affected the skin, peripheral nerves, and mucous membranes. Without early intervention, patients' skin and organs may show signs of inflammation, such as redness, discoloration, or even deformity. If the bacteria attack peripheral nerves, patients may feel numbness over their skin. With the loss of pain sensation over the skin, patients cannot protect themselves and can be subject to all kinds of stimulation from outside without perception, which may lead to severe extremity deformity.

Patients' organs may suffer from severe damage, which makes them prone to symptoms of ulcers over extremities and lesions over distal extremities. Among all the symptoms, nerve damage or function impairment caused by neurological lesions can be particularly difficult to care for. One common example is the loss of sensation over soles of feet, which may develop into ulcers. Subsequently, these ulcers may become chronic nonhealing wounds.

In the pilot study, five patients were recruited, who had 23 wound sites. After 2 months of treatment, the healing rate of ulcers was 50%, 60%, and 100%, respectively, in three patients. This is the crystallization of the wisdom of predecessors. There is no medicine in modern medicine that can exert the same effect.

Therefore, this experiment hopes that the effect of Jinchuang ointment (JCO) can achieve good therapeutic goals and effects, shorten the course of treatment, alleviate the suffering of patients, and reduce medical costs.

2. Aim:

The main research is to treat the wounds of patients with Hansen's disease. When patients with Hansen's disease have wounds, the treatment of wound care is cumbersome. It not only requires frequent dressing changes, but also needs to pay attention to changes in the wound, and moreover, to prevent repetitive wound infections. It can accelerate wound healing by externally applying Chinese medicine Jinchuang ointment (JCO) and also reduce medical costs and nursing manpower (Lewis, 2003 & Vanderwee, 2007).

Therefore, the purpose of this project is to evaluate the healing effect of the Chinese medicine Jinchuang ointment (JCO) on the wounds of patients with Hansen's disease. Therefore, through the four steps of "Observation, Rinsing, Washing, and dressing" wound care, and the original traditional Chinese medicine treatment method for external trauma, the diagnosis and treatment are accelerated. The treatment process reduces unnecessary waste of medical resources, shortens the treatment time, reduces side effects, and saves medical resources.

To create the benefits of both economic and wound healing, and to develop a wound care system for Hansen's disease. It is expected that the completion of wound care for Hansen patients will have a complete record and evaluation.

3. Inclusion Criteria and Exclusion Criteria:

Inclusion Criteria:

(1) Age: 20-85 years old.
(2) Hansen's diseases patients who meet the definition of chronic wound (wounds that do not heal for more than six weeks) are evaluated and screened by doctors as the main target for diagnosis and treatment.

Exclusion Criteria:
Patients with kidney disease, parathyroid disease, and malignant tumors.

4. Methods:

(1) This study will be carried out in the Wound Care Clinic for Hansen's disease Patients in Lo-Sheng Sanatorium of the Ministry of Health and Welfare, Taiwan. For Hansen's disease patients who meet the criteria for inclusion in this study, the principal investigator will explain the contents of the study together with Hansen's disease patient. Implementation method: It is estimated that 20 patients will be admitted. The experiment will be a non-randomized controlled experiment, divided into Jinchuang ointment (JCO) treatment group and control group. According to the implementation method of the study content for patients who meet the conditions for inclusion in this study, they will be added to the treatment group or control according to the patient's wishes. Group and obtain the consent form of the subject.
(2) Experimental: "Jingchuang Ointment"(JCO) group：
Ulcers were treated in this study using the four-step wound care guidelines, observation, rinsing, cleaning, and dressing, published by the Taiwan Food and Drug Administration in 2013. Besides, Jingchuang Ointment (JCO) was applied once a day on the wounds, last 3 months.

"Jingchuang Ointment" (JCO) is made by Chuang Song Zong Pharmaceutical Co., Ltd. (Taiwan)

Fig 1. The four-step wound care guidelines

Fig 2. “Jingchung Ointment” Care Program Standard

(3) Regular treatment group:
Ulcers were treated in this study using the four-step wound care guidelines, observation, rinsing, cleaning, and dressing, published by the Taiwan Food and Drug Administration in 2013.

5. Possible side effects, incidence and treatment methods:
If you experience any discomfort during the application process, such as allergies, redness, swelling, itching, etc., or if the wound continues to deteriorate, please inform the medical staff. You can immediately terminate the treatment and resume the original treatment plan. We A dermatologist will be arranged for diagnosis and treatment, and all expenses will be covered by this plan, and you will not have to pay any fees.

The subject can also terminate the trial at any time during the planning process, and the treatment method before the original case will be restored will be restored.

6. Other alternative therapies and instructions:
No

7. Expected benefits of the project:
Shorten the treatment time, reduce side effects, thereby saving medical resources.

8. The contraindications, restrictions and cooperation items of the subjects in the research project:
(1) Subjects should not soak in water after applying the medicine. The wound should be kept clean and dry. If it gets wet or contaminated accidentally, please inform the medical staff to replace it immediately to prevent deterioration or infection.
(2) When the wound is on the lower limbs, try to avoid standing, hiking, and climbing for a long time, which may cause the wound to deteriorate.
(3) Bedridden patients should do their best to cooperate with bedside care to prevent wound deterioration or regeneration.
(4) Subjects should return to the clinic for regular inspections.

9. Confidentiality:
The personal information of the relevant patients in this project will be unlinked, and only the subject's identification code will represent the subject during the trial. The data is kept in a locked file cabinet in the research room and will be destroyed one year after the end of the research.

(Article 14) By signing the subject consent form, the subject agrees that the original medical records can be directly reviewed by the monitors, auditors, human testing committees and competent authorities to ensure that the clinical trial process and data comply with relevant laws and legal requirements and promise not to violate the confidentiality of the subject’s identity.

(Article 15) The record of identifying subjects shall be kept confidential and will not be made public under the requirements of relevant laws and regulations. If the test results are published, the identity of the subjects will remain confidential.

10. Damage compensation and insurance:
    (1) If an adverse reaction or damage occurs according to the clinical trial plan of this research institute, all the expenses related to the clinical trial will be covered by this plan. This hospital is willing to provide professional medical care and medical consultation, so you do not have to bear the burden of treating the adverse reaction. Or damage necessary medical expenses. However, the expected adverse reactions recorded in the subject's consent form will not be compensated.
    (2) Except for the compensation and medical care in the preceding paragraph, this research does not provide any other forms of compensation. If you are unwilling to accept such risks, please do not participate in the trial.
    (3) You will not lose any legal rights by signing this consent form.
    (4) There is no liability insurance for this study.

11. Subject rights:
    (1) During the trial process, any major discoveries related to your health or disease that may affect your willingness to continue the clinical trial will be provided to you by the research team in real time.
    (2) If you have questions about the content during the trial, or if you have opinions about the rights of a patient or suspect that you have been harmed by participating in the research, you can contact the Medical Ethics and Human Testing Committee of Taoyuan Hospital of the Ministry of Health and Welfare, Taiwan. For consultation, the contact number is: 03-3699721 ext. 8341.
    (3) In order to carry out the study, you must accept the care of Dr. Hsu Wei-Hung. If you have any questions or conditions now or during the trial, you can always contact Dr. Hsu Wei-Hung, Director of the Department of Traditional Chinese Medicine, Lo-Sheng sanatorium, Ministry of Health and Welfare, Taiwan. (24-hour contact number: 09**-***-*** 。
    (4) This consent form is in duplicate. Please confirm that the principal investigator/sub-investigator has given you a copy of the consent form and has fully explained the content and purpose of this research, and please confirm that the principal investigator/sub-investigator has answered your questions about ointment and research.

12. Withdrawal and suspension of the test:
    (1) You are free to decide whether to participate in this trial; you can also withdraw your consent to withdraw from the trial at any time during the trial without any reason. Withdrawing from the trial will not cause any unpleasantness or affect the doctor's medical care in the future.
    (2) The principal investigator may also suspend the test if necessary.

Subject Information

Name:_____

Gender:_____ Date of birth:_____

Name of legal representative / person with the right to consent: _____

Signature

The Principal Investigator or Sub-Investigator has explained in detail the content and purpose of the above-mentioned research methods in this study, as well as the possible risks and benefits.

The Principal Investigator or Sub-Investigator (Signature):

_____

Date:

The subject has a detailed understanding of the above-mentioned research methods and the possible dangers and benefits of the project, and the principal investigator has explained in detail. I agree to accept as a voluntary subject for this project.

Subject (Signature):_____
Date:

or
Legal representative (Signature):_____
Date:

Relationship with subjects:_____

or
Person with the right to consent (Signature):_____
Date:

Relationship with subjects:_____

Witness:

Name:_____ ID Number:_____

Tel:_____

Address:_____

Signature: _____
Date: