Taipei Hospital,

Ministry of Health and Welfare, Taiwan.

ICF

Informed Consent Form

The Effects of Traditional Chinese Medicine Gargle Solutions on the Oral Health of Leprosy Patients

IRB No.: TH-IRB-0021-0012

Study Start: October 1, 2021.

Primary Completion: December 31, 2021.

Taipei Hospital, Ministry of Health and Welfare, Taiwan.

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Version / date: Version 3 / Sep 6, 2021.

Protocol Title:
The Effects of Traditional Chinese Medicine Gargle Solutions on the Oral Health of Leprosy Patients

IRB No.: TH-IRB-0021-0012

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

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- Sub-Investigator: Cheng Hsin-Chong.
  Title: Director of college of Oral Medicine, Taipei Medicine Hospital, Taiwan.

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

1. Aim:
   There is no research on the oral health of Hansen's patients with Chinese medicine treatment methods in the world. The purpose of this research is to treat with Chinese medicine gargle, and through the questionnaire survey of dental plaque detection and xerostomia assessment and the research of Chinese medicine treatment mechanism, and then analyze the relevant data of the oral cavity of Leprosy patients in the early treatment to find the safest and effective treatment method for Leprosy patients.

2. Inclusion Criteria and Exclusion Criteria:

   Inclusion Criteria:
   - Age: 20-85
   - Residents of Lo-Sheng sanatorium of the Ministry of Health and Welfare, Taiwan.
   - Compliant with the presence of more than four teeth in each of the upper and lower four regions
   - Those who have not used antibiotics and gargle two months before the test.

   Exclusion Criteria:
   - Moderate to severe dementia
   - CDR (Clinical Dementia Assessment Scale) is greater than or equal to 2 points or more
   - Those with a score of less than 17 on the MMSE Simple Mind Scale

- Nasogastric Tube Inserters
- Those who are allergic to gargle
- Those who are on course of antibiotics and steroids
- Those who have had dental cleansing within one month

3. Methods:
The implementation method uses clinical data and questionnaire data.

A. Clinical data

a. Secretion of saliva examination:
Measurement method: Measure once before, during and after treatment. Instruct the subject to put the tip of the tongue up against the hard palate, place a dry cotton ball in the mouth of the subject's sublingual caruncle, and take out the cotton ball moistened with saliva after 10 minutes and weigh it. The secretion of saliva was measured one hour after the subject's meal to reduce physiological interference.

Saliva weight (g)
= weight of the cotton ball with saliva - weight of the dry cotton ball

b. Dental plaque examination
Select 14, 21, 26, 31, 36, 44 for evaluation. If the tested tooth is missing, take the nearest tooth for testing. The standard for dental plaque detection uses "Plaque Index" (PLI): Use the Turesky modification of the Quigley-Hein Plaque Index (TQHPI) method to record in six degrees (4):
0 - No plaque
1 - Scattered plaque on the neck of the tooth
2 - The plaque on the neck of the tooth is thin and continuous, with a width of less than 1 mm
3 - Plaque appears below 1/3 of the tooth surface
4 - Plaque appears on the tooth surface between 1/3 ~ 2/3
5 - More than 2/3 of the plaque appears on the tooth surface

c. Xerostomia questionnaire
Used the xerostomia questionnaire (Pai, 2001)
To answer on a 100mm horizontal scale, there are eight questions in total:
(a) The proportion of people who have difficulty speaking due to dryness
(b) Proportion of people having trouble of swallowing due to dryness
(c) Saliva volume in the mouth
(d) Degree of dry mouth
(e) The degree of dryness of the throat
(f) Degree of dryness of lips
(g) Degree of dry tongue
(h) Degree of thirst

B. Experimental method

a. Traditional Chinese Medicine Gargle
The gargle used in this test is based on the records of past traditional Chinese

medicine classics and the existing antibacterial experimental evidence. The selected medicinal materials are honeysuckle, scutellaria, peppermint, licorice, and rhizome.

- Experimental group: use traditional Chinese medicine gargle
- Control group: use Chinese medicine gargle diluted 50 times

b. Test procedure

Before the test, the test subject's xerostomia questionnaire and PLI were tested and recorded, and then an ultrasonic dental scaler was used to clean each tested tooth and adjacent teeth (Scodyl). The plaque display agent will stain the plaque. Make sure that PLI = 0. The experiment can be started on the same day. During the experiment, the subjects must stop all mechanical cleaning measures such as brushing their teeth.

The subjects gargle and use traditional Chinese medicine gargle after three meals a day and before going to bed, four times a day for 7 consecutive days. After 7 days, record the PLI value and conduct a xerostomia questionnaire, and then retrieve the gargle bottle the remaining dose was checked to judge compliance. Those with significantly poor compliance were excluded from the experiment, and then the daily cleaning measures were resumed. The subjects still followed the way of gargle four times a day until the end of the 21st day after the xerostomia questionnaire.

After three meals a day and before going to bed, gargle four times, each gargle time is 30 seconds, each time 20 ml, do not eat within one hour after gargle. During the test period, avoid eating sticky foods or sweets such as candies, and prohibit the consumption of chewing gum, alcohol, and beverages.

Before the examination, the subjects must rinse their mouth twice with clean water, keep them moisturized, and blow dry. Use a cotton swab to dip Scodyl dental plaque display agent to stain the surface of each tested tooth, stay for 30 seconds, and then rinse the mouth with clean water. Observe and record the PLI value of the tooth surface. The sample content is calculated on a per-tooth basis, and a total of six teeth are selected. The observations of each subject are interpreted by the same researcher at the same time, place, and lighting conditions.

4. Possible side effects, incidence, and treatment methods:
This study uses questionnaires, saliva collection and dental plaque detection, and there are no side effects and risks. The elements of the traditional Chinese medicine gargle used in the experiment are all components that can be taken by the public and can also be taken orally. If the subject swallows the gargle during the gargle process, it will not harm health or pose a risk.

5. Other alternative therapies and instructions:
No.

6. The research subject has the right to withdraw consent at any time and the method of withdrawal:

   Participants have plenty of time to decide whether to participate in this research project. If participants do not want to continue participating, participants can freely decide to quit at any time without providing any reason. Withdrawing from this research will not affect any of participants legitimate medical rights. The principle of this project, Hsu Wei-Hung, is willing to provide appropriate and necessary assistance during the research process.

   Withdraw from the study halfway, the processing method of my data:
   ☐ I do not agree that the collected and analyzed samples and data will continue to be used (but those who can no longer link to personal data or who have been publicly published are not limited to this).
   ☐ I agree that the collected and analyzed samples and data will continue to be used.
   ☐ I do not agree that the collected samples and data are used, but I agree that the analyzed samples and data can continue to be used.
   ☐ I do not agree that the collected and analyzed samples and data will continue to be used (but those who can no longer link to personal data or who have been publicly published are not limited to this).

7. After the research is completed, the storage period of the research materials and the description of the application plan:
   The cotton balls containing saliva in the research will be destroyed immediately after the completion of the human test according to Article 14 of the human test management method.

8. Confidentiality and the interviewee's personal data protection mechanism:
   A. 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 regulations, To ensure that the clinical trial process and data comply with relevant laws and regulations, and promise not to violate the confidentiality of the subject's identity. The record of identifying the subject shall be kept confidential and will not be made public under the requirements of relevant laws and regulations.
   B. The executing agency of this project will safeguard participants rights and interests during the test process.
   C. The information obtained may be published in academic journals, but participants name will not be published, and participants privacy will be kept strictly confidential.
   D. Participants can withdraw participants consent at any time during the research process and withdraw from the inspection.

9. Relief measures in case of injury:
   A. If adverse reactions or injury occur because of the clinical trial plan set by this research institute, our hospital will provide professional medical care and medical consultation. Participants do not have to pay the necessary medical expenses for the treatment of adverse reactions or injury.

B. Except for the compensation and medical treatment mentioned in the preceding paragraph, this research does not provide any compensation. If participants are unwilling to accept such risks, please do not participate in the trial.
C. Participants will not lose any legal rights by signing this consent form.

10. The source of research funding, the expected benefits of the experiment, the commercial benefits that may be derived from the research and the agreement on its application:
    A. Source of funding: None.
    B. The clinical benefits that can be reasonably expected to participate in the research:
       a. Subjects who have undergone saliva secretion test and dental plaque examination can obtain the test results of saliva secretion and dental plaque.
       b. Provide institutional nurses with assessment of oral health status.
       c. Provide the basis for the need for dental treatment.
    C. If the research results of this project obtain academic publication, intellectual property, substantial benefits, or derived other rights, participants will agree to transfer free of charge to the Lo-Sheng Sanatorium of the Ministry of Health and Welfare for medical purposes such as disease diagnosis, prevention, treatment, and research.

11. Research object rights:
    A. Participants do not need to pay any additional expenses during the study period.
    B. During the research process, any major discoveries related to participants health or illness that may affect participants continued acceptance of the research plan will be immediately provided to participants or participants legal representative.
    C. If participants have questions about the research plan during the research process or have opinions about the rights of the research subject or suspect that participants have been harmed by participating in the research, participants can contact the Human Testing Committee of the Taipei Hospital of the Ministry of Health and Welfare for consultation. The phone number is: 02-22765566 ext. 3204; e-mail: irb@tph.mohw.gov.tw or mail to 24213, No. 127, Siyuan Road, Xinzhuang District, New Taipei City / Human Test Review Committee.
    D. If participants have any questions or conditions during the study period, please feel free to contact with Dr. Hsu Wei-Hung at Lo-Sheng sanatorium, the Ministry of Health and Welfare (24-hour contact number: 09**-***-***).
    E. This consent form is in duplicate. The researcher has given participants a copy of the consent form and has fully explained the nature and purpose of this research.
    F. The principle of the project, Dr. Hsu Wei-Hung, has answered participants questions related to the research.

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: