Clinical Research

Project Name: Study of the Therapeutic Effects of Naohuan Dan and Idebenone in Treating Mild Cognitive Impairment With Kidney Deficiency and Phlegm Stasis

Bidding unit: Sun Yat-sen Memorial Hospital, Sun Yat-sen University

Version number: v1.0

Version date: 30/08/2022

Project manager: Qihui Huang

Informed Consent · Informed Information Page

Dear patient,

The doctor has diagnosed you with mild cognitive impairment. We would like to invite you to participate in a clinical observation study on the treatment of mild cognitive impairment of the kidney-deficiency and phlegm-blood stasis types with Naohuan Dan and Idebenone. This study is funded by the Guangdong Natural Science Foundation, project number: 2019A1515011414. The study protocol has been approved by the Ethics Committee of Sun Yat-sen Memorial Hospital, Sun Yat-sen University.

Before you decide whether to participate in this study, please read the following information carefully to the best of your ability. It will help you understand the purpose of the study, the procedures and timeline involved, and the potential benefits, risks and discomfort that may arise from your participation. If you wish, you may also discuss this with your family and friends, or seek explanation from your physician to assist you in making the decision.

1 Research Background and Purpose

1.1 Background

Mild cognitive impairment (MCI), a transitional state between aging and dementia, is clinically characterized by a decline in cognitive function, but daily living abilities remain unaffected or mildly impaired. Previous studies have shown that 50% of MCI patients will progress to dementia within 3-4 years of onset, and the proportion of individuals progressing to dementia increases with age and disease duration. A meta-analysis using a random-effects model showed that the cumulative incidence rate of dementia for MCI patients aged 65 and above after 2 years was 14.9%. As the aging of the population accelerates in China and life expectancy gradually increases, the incidence rate of MCI is on the rise.

Based on the above research background, we believe that the combination of Naohuan Dan combined with Idebenone has great application prospects for the treatment of Kidney Deficiency Phlegm Stagnation Type MCI. To this end, we have designed a clinical study to evaluate the efficacy and safety of the combination of Naohuan Dan combined with Idebenone for the treatment of MCI, by assessing relevant cognitive function rating scales and TCM syndrome scores. This study aims to provide valuable information for the integration of TCM

and Western medicine in the treatment of MCI.

1.2 Research purposes

This study evaluated the efficacy of Naohuan Dan combined with Idebenone for treating MCI patients with Kidney-Deficient and Phlegm-Stasis syndrome. Changes in cognitive function, daily living abilities, depression levels, and Traditional Chinese Medicine clinical symptoms were assessed using relevant rating scales, and compared with the efficacy of Idebenone alone, demonstrating the advantages of combining traditional Chinese and Western medicine in treatment.

1.3 Research participating units and expected number of participants

This study was mainly conducted at the Sun Yat-sen Memorial Hospital of Sun Yat-sen University, and 64 participants were expected to be enrolled.

2 Inclusion and Exclusion Criteria

The following inclusion criteria were used: (1) diagnosis in line with Chinese medicine and Western medicine; (2) suitable for age 55-85 years old, gender is not limited; (3) a score between 21-26 on Mini-Mental State Examination (MMSE), 1 point for primary school education; (4) agree to take part in this experiment and sign the informed consent form.

The following exclusion criteria were used: (1) patients with severely impaired heart, liver, kidney and other functions; (2) patients with neurological diseases that affect brain function and cognitive impairment; (3) patients with severe depression and mental illness; (4) patients with poor compliance and cooperation who failed to complete the study according to the protocol.

3 What will I need to do if I take part in the research?

Before being enrolled in the study, your doctor will ask about and record your medical history, assess your condition, and determine if you meet the inclusion criteria. If you voluntarily agree to participate in the study and meet the criteria, you will be asked to sign an informed consent form. However, if you choose not to participate, it will not result in any bias

or impact on your medical care.

If you voluntarily participate in this study, the following steps will be taken:

Upon admission, the subjects will undergo routine admission examinations, and the physician will arrange for the subjects to undergo routine examinations and body composition analysis. The purpose of this study is to collect and store clinical data and blood specimens from patients with mild cognitive impairment. The clinical data include general information, medical history, laboratory examinations, electrocardiogram, and body composition analysis. This study will not intervene or interfere with your treatment.

During the course of the research project, it is possible that new information regarding the research methods may arise. If this occurs, your research doctor will inform you in a timely manner and discuss with you whether you are willing to continue participating in the study. If you decide to continue, you may be asked to sign a new informed consent form. During the follow-up phase, the doctor may contact you through phone or outpatient visits to keep track of your condition.

4 Possible benefits of participating in research

If you choose to participate in this study, there is a possibility that your condition will be promptly evaluated and subsequently guided for treatment, but there is no guarantee. You will not receive any form of direct financial benefit from this study.

5 Possible adverse reactions, risks, discomfort and inconvenience of participating in the research

If you experience any discomfort, new changes in your condition, or any unexpected situations during the study period, whether related to the research or not, please inform your doctor promptly. They will assess the situation and provide appropriate medical treatment.

6 Confidentiality of Personal Information

During the course of the study, any information or data obtained about you personally will be kept strictly confidential. Your blood samples will be identified using a research code/number rather than your name, and any identifying information will not be disclosed to

anyone outside of the research team without your permission. Any public reports regarding the results of this study will not reveal your personal identity. We will make every effort to protect the privacy of your personal medical information within the scope of the law.

According to medical research ethics, except for personal privacy information, the research data will be available for public inquiry and sharing, and the inquiries and sharing will be limited to web-based electronic databases to ensure that no personal privacy information will be leaked.

7 How can I get more information?

You can raise any questions related to this research at any time and receive corresponding answers. If there is any important new information during the research process that may affect your willingness to continue participating, your doctor will notify you promptly.

8 You can voluntarily choose to participate in the study and to withdraw from the study

Whether you participate in this study is entirely up to your own will. You have the right to decline participation in this research, or to withdraw from the study at any time, without affecting your relationship with your doctor or incurring any other potential losses or disadvantages. In the interest of your maximum benefit, the physician or researcher may also suspend your participation in this study at any time.

9 what to do now

The decision of whether to participate in this study is entirely up to you (and your family). Before making a decision to participate, please consult your physician with any questions you may have.

Thank you for reading the above information. If you decide to participate in this study, please inform your physician who will arrange everything related to the study for you. Please keep this material for your reference.

Informed Consent Form. Consent Signature Page

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Subject undertaking unit: Sun Yat-sen Memorial Hospital，Sun Yat-sen University

Task book number: 2019A1515011414

Consent Statement

I have read the description of this study and had the opportunity to discuss and ask questions with my doctor. All of my questions have been satisfactorily answered.

I understand the risks and benefits of participating in this study. I confirm that my participation is voluntary and that I have had sufficient time to consider it. I also understand that:

- I can consult my doctor for more information at any time.
- I can withdraw from the study at any time without discrimination or retaliation, and that my medical treatment and rights will not be affected.

I am also aware that if I decide to withdraw from the study, especially due to medication-related reasons, it would be beneficial for the study if I inform my doctor of any changes in my condition, complete the necessary physical and chemical examinations.

If I require any other medication for my condition during the course of the study, I will seek my doctor's advice in advance or truthfully report it to my doctor afterwards.

I agree that the ethics committee of the drug regulatory agency and/or sponsor representative can access my research data.

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

Finally, I have decided to agree to participate in this study and promise to follow my doctor's advice to the best of my ability.

Patient Signature：_____ Date：_____

Contact Number：_____

I confirm that I have explained the detailed information of this trial to the patient, including their rights and possible benefits and risks, and have provided them with a signed copy of the informed consent form.

Doctor's Signature：_____ Date：_____

Doctor's Work Phone：_____