Acupuncture Treatment for Knee Osteoarthritis With Sensitive Acupoints and Tender Points (A multicenter randomized controlled trial)

ClinicalTrials.gov identifier: NCT03299439

PARTICIPANT INFORMED CONSENT

West China Hospital of Sichuan University

January 10, 2017

Dear Participant,

You are diagnosed with Knee osteoarthritis (KOA) by your doctor. We invite you to participate in a multi-center randomized controlled trial of acupuncture treatment on knee osteoarthritis. This trial is one of the study projects supported by the National Natural Science Foundation of China (grant number 81590955).

Before you decide to participate in this trial, please read the following information as carefully as possible. It can help you understand why it is conducted; the procedures and duration of the study; the benefits, risks, and discomfort that might occur to you. If you have any remaining queries, please ask your doctor who may answer your questions in more detail. If you wish, you also can discuss with your family or friends, or ask your doctor to facilitate your decision.

About the Research

1. Background and the study objective

Acupuncture represents an important alternative treatment option for patients with knee KOA. According to the theory of traditional Chinese medicine and preliminary clinical evidence, certain acupoints and ashi points within the medial regions of knee in patients with KOA were sensitized, particularly presenting as pain. Stimulation of such pain-sensitized points could lead to improvement of disease conditions. The pressure pain threshold (PPT) is a valid and reliable measure of quantifiable localized pain, reflecting the magnitude of pain sensitivity. It is hypothesized that acupuncture at higher sensitized (lower PPT) points on KOA patients would achieve better treatment outcomes than acupuncture at lower sensitized (higher PPT) points.

In this study, we aim to examine whether acupuncture at acupoints with higher pain sensitivity (lower PPT) was more efficacious than lower pain sensitivity (higher PPT)

This Three-arm, parallel, 16-week trial will be conducted at the Affiliated Hospital of Chengdu University of Traditional Chinese Medicine, West China Hospital of Sichuan University, the Third Affiliated Hospital of Henan University of Traditional Chinese Medicine, and Wuhan Integrated Traditional Chinese Medicine and Western Medicine Hospital, and is expected to recruit 666 subjects.

2. Patients are not suitable for the study if they meet any of the following:

1) Diagnosed with conditions that may lead to skeletal disorders, such as tuberculosis, tumors or rheumatism of the knee joint and rheumatoid arthritis;
2) Presence with sprain or trauma in the lower limb;
3) Unable to walk properly due to foot deformity or pain;
4) Cannot answer questionnaire due to mental disorders and/or intellectual disability;
5) Presence with comorbidities, including severe cardiovascular disease, liver or kidney impairment, immunodeficiency, diabetes mellitus, blood disorder or skin disease;
6) Females who are pregnant or lactating;
7) Are using or have used physiotherapy treatments for osteoarthritis knee pain in the past month;
8) Have used intra-articular injection of glucocorticoid or viscosupplementation in the past six months;
9) Received knee-replacement surgery on the affected side(s);
10) Diagnosed with severe (stage 4, according to Kellgren and Lawrence radiographic classification) or late clinical stage of KOA;
11) Have a swollen knee or positive result of floating patella test;
12) Are participating in the other clinical trials of acupuncture.

3. What will be needed to participate in the study?

Before you are selected for the study, you will receive the following examinations to determine whether you can participate:

The doctor will ask and record your medical history and have a physical examination for you. You need blood routine, liver function, kidney function, electrocardiogram, knee X-ray examination. Doctors may also conduct other laboratory tests depending on your clinical situation. You need to take blood before entering the group. All of the above tests are free of charge, which will help the doctor to understand your condition in a more comprehensive and detailed way. These tests are safe and will not adversely affect your health or illness.

If you pass the above screening and meet the inclusion criteria, the following steps will be followed:

A: Eligible patients who consent to participate will be randomly assigned to higher sensitization group (patients receive acupuncture at acupoints with lower PPT), a lower sensitization group (patients receive acupuncture at acupoints with higher PPT) or a waiting-list group (no acupuncture) via a central randomization system by the same chance. Neither you nor your acupuncturist can know and choose a treatment in advance.

Participants in the higher and lower sensitization groups receive acupuncture stimulation lasts for 30 minutes. Participants receive three treatment sessions per week (every other day) for four consecutive weeks.

All the participants will be advised not to take any other treatments for KOA. However, NSAIDs are allowed if participants have intolerable pain and the outcome assessment is not scheduled in the next 48 hours. All such treatments (including drug name, dosage and duration of treatment) that patients received are documented during the study. Patients are assessed at baseline and 4, 8, 12, and 16 weeks after randomization.

B: Participants will be asked to document all such treatments (including the name, dosage/frequency and duration of treatment) receiving for KOA.

C: After the treatment, the observation physician will record your symptoms and signs in detail.

D: The above treatment and examination related to this trial are free of charge.

E: Sterile, single-use filiform acupuncture needles (Hwato Needles, Sino-foreign Joint Venture Suzhou Hwato Medical Instruments Co., China) with a length of 40 mm and a diameter of 0.30 mm will be used in the treatment.

F: Ethics approval has been granted by the Bioethics Subcommittee of West China Hospital, Sichuan University

Other matters requiring your support

You should come to the hospital at the time of scheduled follow-up that you have with the doctor. Your follow-up is important because your doctor will determine if your treatment really works and provide timely guidance. It is also your responsibility to tell your doctor any changes in your physical and mental health during the trial, whether you believe the changes are related to this study or not.

During the study, please follow the doctor's recommendation and fill in your medication record timely and carefully. You must bring other medications (including health care products) you are taking at each follow-up visit, including other medications you have to continue to take if you have a complicated illness.

If you need additional treatment, please contact your doctor in advance.

4. Possible benefits

You may benefit from this study. This benefit includes the possibility of improvement in your condition. If you participate in this study, you will receive free physical and chemical examination and treatment, which are related to this study, during the study period.

5. Possible adverse events, risks, discomfort and inconvenience

You may feel acid, numbness, weight and swelling in the process of acupuncture, which is the normal reaction of acupuncture. There may be adverse events after acupuncture, but it is rare and mild. You may get seasickness due to your physical problems or emotional tension during the acupuncture process. Bleeding and hematoma may appear after acupuncture and disappear after local pressing. But if the needle point is infected, your doctor will carefully handle it.

If you have any discomfort during the study period, illness, or any unexpected events, no matter whether they are associated with acupuncture treatment, you should promptly notify your doctor, he/she will examine the issues and offer appropriate medical care.

You will be followed up at the hospital during the study and receive some

examinations, which may cause trouble or inconvenience to you.

6. Related cost

Doctors will do their best to prevent and treat possible injuries as a result of this study. If adverse events occur in this clinical trial, the medical expert committee will determine whether they are related to acupuncture treatment or the trial process.

During the treatment period, the treatment and examination required for other diseases that you combine with will not free.

7. Is personal information confidential?

Your medical records (research medical records, laboratory tests, etc.) will be kept intact at your hospital. The doctor will record the results of examinations on your medical record. Researchers of this trial, ethic committee members, and the committee members from the grant body (i.e. the National Natural Science Foundation of China) are allowed to access your medical records. Your personal identity will not be disclosed in any public report. We will make every effort to protect the privacy of your personal medical data.

8. How can I get more information?

You can ask any questions about this study at any time and get answers accordingly. Your doctor will keep you informed of any important new information that may affect your willingness to continue the study.

9. You may choose to participate in the study or withdraw from the study on a voluntary basis

Whether you participate in the study is totally up to you. You can refuse to participate, or withdraw from this study at any time during the course of the research. This will not affect the relationship between you and the doctor.

For the best interest of you, a doctor or researcher may discontinue your participation at any time during the study.

If you withdraw from the study for any reason, you may be asked about your

acupuncture treatment. You may also be required to have a laboratory and physical examination if the doctor deems it necessary.

10. What should I do now?

It is up to you to participate in this study.

Please ask your doctor as many questions as possible before you make your decision to participate in the study.

Thank you for reading this document. If you decide to participate in this study, please tell your doctor, so that he/she will arrange for you all matters related to the study. Please keep this information.

11. Consultation or complaint

If you have any questions, suggestions or complaints about this study, please discuss with the research team.