

**The KeyPlan of Zhejiang Province
Traditional Chinese Medicine Prevention and
Treatment of Major Diseases**

Number: 2018ZY008

Research name:

**Different kinds of acupuncture treatments for Knee
Osteoarthritis: a Multi-center Randomized controlled
trial**

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Informed Consent· Informed Notice Page

Dear participants:

We sincerely invite you to participate in "Multi-center Randomized Controlled Trials on Acupuncture for Knee Osteoarthritis", granted by the Zhejiang Provincial Chinese medicine prevention and treatment of major diseases research project "Multi-center Randomized Controlled Trials on Acupuncture for Chronic Pain", project number: 2018ZY008. Four different acupuncture treatments are proposed to treat knee osteoarthritis. Compared with drug (Celebrex) and sham-needle. Through this clinical study, A scientific assessment of the treatment of knee osteoarthritis with four different acupuncture methods. Please read the following carefully. It can help you understand the details of the study. If you want, you can also discuss with your relatives or friends, or ask the doctor to explain it and help you make a decision.

1. Research Introduction

Knee Osteoarthritis (KOA) is a common osteoarthropathy. According to the World Health Organization (WHO), about 10% people in the world over the age of 60 have symptoms of knee osteoarthritis, which is up to 19.4% in China. With surging of the population aging, KOA will become the world's fourth most disabling disease by 2020. The main symptoms of knee osteoarthritis include persistent pain around the knee joint, motion pain or rest night pain, numbness, joint stiffness and flexion and extension restriction. KOA seriously affect the life quality of patients, although patients with knee osteoarthritis can relieve pain by taking non-steroidal anti-inflammatory drugs (such as celecoxib, acetaminophen, etc.) or other drugs , there are liver damage, Gastrointestinal toxicity and other side effects. Acupuncture treatment of knee osteoarthritis has an anti-inflammatory and analgesic effect, not only ease knee pain, but also improve the symptoms of KOA and life quality. To scientifically evaluate the efficacy and clinical value of acupuncture in the treatment of knee osteoarthritis, the Third Affiliated Hospital of Zhejiang Chinese Medical University jointly conducted this study with 5 other hospitals.

2.Exclusion criteria

- 1) Knee osteoarthritis patients with gout, infection, tumor, autoimmune diseases,

trauma or other causes of knee pain or knee deformities;

2)Patients who have local skin damage, poor skin conditions or coagulant dysfunction and patients who are not suitable for acupuncture;

3)Patients who are accompanied with serious medical problems or mental disorders, cognitive dysfunction or who cannot cooperate with the treatment;

4)Patients who have received acupuncture or needle knife in the past month;

5)Other patients who are not suitable for acupuncture treatment.

3. Who can take part in this study?

3.1 You may be eligible to take part in this research study. This form gives you important information about the study if you are eligible:

Doctor will ask and record your medical history, perform a medical examination and do a knee X-ray at the same time. If necessary, we will check blood tests, biochemistry, coagulation, tumor markers, and rheumatoid factor to confirm the diagnosis.

3.2 What exactly will be done to me in this study? What kinds of research procedures will I receive if I agree to take part in this study:

(1) Based on the random numbers provided by the computer, participants are randomized into one of the six treatment groups. There are standardized acupuncture group, electro-acupuncture group, mild moxibustion group, warm-needling acupuncture group, sham acupuncture group and western medicine group. Participants in Western medicine group are treated with Celebrex capsules. The anti-inflammatory effects of the drug are mainly due to its ability to inhibit prostaglandin production by cyclooxygenase-2 (COX-2).The drug can effectively relieve the symptoms of osteoarthritis.

(2)The study period is 6 months including baseline(2 weeks before treatment), 4 weeks(treatment period) and 6 months(follow-up period).Participants in all acupuncture groups receive 12 treatment sessions within 4 weeks(3 times a week). Western medicine group participants need to receive treatment for 4 weeks. No treatment will be carried out in the follow-up period . All the cost of acupuncture treatment and drug will be covered by the research group.

(3) During the study, you need to describe honestly about the pain and related symptoms in detail at the fixed time. And you need to complete the relevant questionnaire.

3.3 Other things that need your cooperation

As a subject of this study, you have some responsibilities, such as getting to the hospital for treatment and checking on time and receiving outpatient visits. It is also your responsibility to report to the doctor any changes in your body and mind during the test, whether or not you think the change relates to this study.

Other analgesics should not be used during the study period. However, if the pain is unbearable, oral administration of Celebrex Capsules (Celecoxib capsule, Pfizer Pharmaceutical Co., Ltd.) may be given orally at 0.2g once daily. The use of emergency drugs should be recorded on the record sheets of drugs and other analgesic measures at any time, indicating the date and time of usage as well as the dosage used. Other analgesics are not required in principle .If used, please also record them on this form. The date , time and dose of emergency medicine, analgesic Chinese medicine or other analgesic measures used must be credited to the appropriate date of the diary card. Emergency medication is available during screening and baseline evaluations. However, emergency treatment is not used within 48 hours before and after the start of treatment to assess the time to complete remission of the first pain and help us better assess your condition.

You must visit the doctor during the study period and follow-up period (during the follow-up period, the doctor may know your situation by phone). Your follow-up is important because the doctor will determine if the treatment you are receiving is actually working and promptly guide you in the prevention and control of the condition.

4.How could I benefit if I take part in this study?

By participating in this study, you will receive free acupuncture and medication for 4 weeks and you will also receive a comprehensive medical education on knee osteoarthritis.

Participants will receive free knee-related inspection and evaluation provided by

the research group.

5. What happens if I get hurt, become sick, or have other problems as a result of this research?

Doctors will take steps to minimize the harm caused by this study.

During the acupuncture treatment, you may feel some normal acupuncture reaction, such as local soreness, numbness, distention and heaviness feelings . Acupuncture treatment may have little adverse reaction. Some patients may get faint during acupuncture treatment because of physical or emotional disorders. In this case , we will stop acupuncture immediately and after some rest patients would get better . It is also possible patients get bleeding, hematoma and other phenomena after acupuncture, local pressure should be given to stop bleeding. If the skin gets burnt when doing moxibustion, doctor will handle it in time.

Few participants taking celecoxib capsules may have side effects such as diarrhea, abdominal pain, headache and palpitations, but mostly they are mild with no interruption of treatment, and return to normal after a dose reduction or withdrawal.

Please note: It is important that you tell the researchers and your regular doctors about any injuries, side effects, or other problems that you experience during this study.

6.The cost.

If you participate in this study, medications and treatments are free. If there is an adverse event in the clinical trial, the Medical Expert Committee will identify whether it is related to the course of the trial. If the damage is related to the research, the research group will pay your medical expenses. However, treatment and inspection of other diseases will not be free of charge.

7.Is personal information confidential?

All information you have brought into this study will be kept confidential and in charge by the subject unit and your research unit. Only the unit is responsible for the study, Clinical trial research units and Ethics committees will have direct access to your case history. Your name will not appear in any published information or report in this study.

We will make great efforts to protect the privacy of personal medical information by law.

8.How to get more information?

You can submit any questions about this study at any time and get the corresponding answers.

If there is any significant new information in the research process that may affect your willingness to participate in the study, your doctor will inform you in time.

9.Can I volunteer to participate in the study and withdraw from the study?

Whether or not to participate is entirely up to you. You can refuse to participate in the study, or withdraw from this study at any time during the course of the research. The relationship between you and the doctor will not be affected, nor will the medical treatment and the rights.

For your maximum benefit, doctors or researchers may suspend your participation in this study at any time during the course of the study.

If you withdraw from the study for any reason, you may be asked about your use of acupuncture or medication. If the doctor deems it necessary, you may also be required to perform laboratory and physical examination.

The office number of Ethics Committee of The Third Affiliated Hospital of Zhejiang Chinese Medical University: 0571-88393504.If you have any complaints, please contact them.

10.What should you do now?

It is up to you (and your family) to take part in this study.

Before you make your decision to participate in the study, please ask your doctor questions about the study as much as possible.

Thank you for reading the above material. If you decide to take part in this study, please tell your doctor that he/she will arrange everything for you.

Please keep this information.

Informed consent· Signature page

Consent statement

I have read the research materials carefully and have the opportunity to discuss and raise questions with the doctor about this study. All my questions have been answered satisfactorily. I fully understand the information about medical research and the risks and benefits that this study may bring. I confirm that I have sufficient time to consider it, knowing that participation in the study is voluntary and understanding:

I can always consult doctors for more information.

I can withdraw from this study at any time without discrimination or retaliation, and medical treatment and rights and interests will not be affected.

I agree with the Bid for the unit, Clinical trial research units and Ethics committee to review my research materials.

I shall obtain a copy of the informed consent form signed and dated.

Finally, I decided to agree to participate in this study and pledged to follow my doctor's advice.

Patient's signature: Date:

Contact number:

Doctor's statement

I confirm that I have explained to the patient the details of this trial, including his or her rights, risks and possible benefits, and a copy of a signed informed consent.

Researchers sign: Date:

Investigator's work phone:

Cell-phone number:

" Different kinds of acupuncture treatments for Knee Osteoarthritis: a Multi-center Randomized controlled trial " is the first topic of "Multi-center Randomized Controlled Trials on Acupuncture for Chronic Pain", project number: 2018ZY008.