Needling Techniques for Tonifying Kidneys and Dredging Meridians for Knee Osteoarthritis: A Randomized Clinical Trial
NCT05014542

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INFORMED CONSENT TO PARTICIPATE IN RESEARCH

RESEARCH TITLE The effects of acupuncture as an additional therapy for osteoarthritis of the knee assessed by renowned questionnaires

PLACE OF RESEARCH Zagreb, Sesvete, Ninska 10

NAME AND SURNAME OF RESEARCH MANAGER Svijetlana Perčulija Đurđević

Dear Sir,

We invite you to take part in a scientific study examining the effect of acupuncture on pain and improvement of skin function in patients suffering from osteoarthritis of the knee. The research is open, the total number of respondents will be divided into two groups, acupuncture and control. Patients will not be compensated for participating in the study. It is expected that patients will be motivated to complete the trial due to the benefits of the therapy received. Patients in the acupuncture group were additionally motivated to complete the trial because of possible additional effects of acupuncture on other symptoms related to the underlying cause of the disorder. Patients in the control group who complete the study by completing the provided questionnaires will be offered the same therapeutic protocol as patients in the acupuncture group, after the study has ended.

We want you to participate in the research because you suffer from knee osteoarthritis. The leader of the research is Svijetlana Perčulija Đurđević, MD, specialist in family medicine, acupuncturist. The research will be carried out in the Private Specialist Practice he runs at Ninska 10, Sesvete, and it is financed independently. The research is conducted for the purpose of creating a doctorate. Please read carefully this Informed Consent for Research Participation, which explains why the study is being conducted and what the risks to your health might be if you agree to participate.

If you do not understand any part of the Informed Consent, please contact the research examiner for an explanation. Your participation in this trial is voluntary and you may withdraw at any time. If you decide to participate in this research, you will be asked to sign an Informed Consent with an indication of the date. The informed consent is also signed by the researcher, and you will receive a signed copy of the informed consent in person before the start of the said research. The original Informed Consent is with the researcher of this trial.

The physician-researcher conducting this research will not receive any financial compensation.

RESEARCH DATA

The research aims to confirm the positive effect of acupuncture as an additional therapy to drug therapy for patients suffering from chronic osteoarthritis. A total of 64 patients will be divided into two groups. The acupuncture group will receive their chronic pain pill therapy that they have previously received with acupuncture, while the control group will only receive their chronic pain pill therapy. The evaluation of the effect of the therapy will be measured with three different questionnaires every three weeks from the beginning of the trial. Acupuncture therapy will be provided in three cycles of three weeks, three times a week. The interval between cycles will be three weeks. The duration of each acupuncture treatment will be 30 minutes. Patients will be admitted at the time they are ordered for treatment. The study ends with the last filling of the questionnaire in the 24th week of the study (9 weeks from the last treatment).

Patients will be randomly selected into groups (like a coin toss). Patients from the group that will not receive acupuncture, upon completion of the trial, will be able to receive the same therapeutic

protocol described above. and other possible positive effects on the health of patients related to the disorder causing the disease under investigation.

What is expected of the respondents

At each individual meeting, the patient will be treated with acupuncture needles that are disposable and sterile, the place where the needle is placed will be previously disinfected with alcohol. The patient will be placed a total of around 10 needles during the treatment, locally in the knee area and a few in more distant places. Each subject will receive a total of 27 acupuncture treatments in 15 weeks. Acupuncture therapy will be provided in three cycles of three weeks, three times a week. The interval between cycles will be three weeks. The duration of each acupuncture treatment will be 30 minutes. The trial is planned to begin in September, 2021.

Patients in both groups will be given three different questionnaires to examine their own symptoms every three weeks from the beginning of the study until the end at week 24.

POSSIBLE RISKS AND INCONVENIENCES!

This research does not involve any risk other than normal everyday risk.

POSSIBLE BENEFITS: you may have the following benefits from participating in the trial: reduction of pain in the knee/knees, improvement of knee function, possible additional positive effects on health.

CONFIDENTIALITY AND PROTECTION OF PERSONAL DATA

The personal medical data of the respondents will be protected. Each respondent will be assigned a code, and the data will be visible only to the examiner. The database will be stored in a computer, and access to the computer will be protected by a code.

Research data will be stored by the examiner for a period of 10 years.

The data in the research will not be used for further research.

According to the data protection law of the European Union (Data Protection Directive, which was replaced by the General Data Protection Regulation on May 25, 2018), your researcher makes important decisions in the use and disclosure of your personal data and, as the "controller", will be jointly responsible for compliance with that law.

Through the researcher, you have the right to access all data collected about you and to request their corrections if they are incorrect during the conduct of the research/after the end of active participation in the research.

You have the right to complain about the way your data is handled, and you can send it to the competent authority responsible for the enforcement of the law on the protection of personal data. The list of competent authorities in the European Union is available at this link: http://ec.europa.eu/justice/data-protection/article29/structure/data-protection-authorities/index_en.htm. For the Republic of Croatia, the competent authority to which you can send a complaint is the Personal Data Protection Agency, Selska cesta 136, HR - 10 000 Zagreb.

If you withdraw from the research, data collected before your withdrawal may still be processed together with other data collected as part of the research.

This research can only be conducted by collecting and using the personal data of respondents in the manner described in this informed consent, and you can participate in it only if you agree to it.

If you have any questions, comments or complaints regarding the way your data is handled, you should first contact the researcher, who will forward your request to the staff responsible for data protection.

BENEFIT FOR THE RESEARCHER

The results of the research will be used for the purpose of creating the examiner's doctoral thesis.

WHO APPROVED THIS RESEARCH

This research was approved by the ethics committee of the Health Center Zagreb-istok, Švarcova 20, Zagreb.

VOLUNTARY PARTICIPATION

Participation in this research is completely voluntary. Your decision on whether or not you want to participate in this research will in no way affect the way, procedures and course of your treatment. If you decide to participate in the research, you can stop your participation in it at any time. You will inform the researcher of your decision in writing (address provided in this survey). The decision to stop participating in the research will in no way affect the way, procedures and course of your treatment.

QUESTIONS ABOUT THE TEST AND CONTACT INFORMATION

For additional questions about the research itself, you can contact Svitelana Perčulija Đurđević, MD, tel. 012050758.

If you fall ill or suffer an injury during this examination, please contact the researcher Svijetlana Perčulija Đurđević, MD, tel. 012050758.

Read this text together with the researcher and/or family members.

With my signature, I confirm that I am informed about the goals, advantages and risks of this research and I agree to participate in it:

In Zagreb, _____ (Date).

_____ _____

Signature of the participant or his Signature of the research leader

of the legal representative

(indicate here the name and surname and the title of the researcher, institution)

I, the research doctor confirm that I have verbally provided the necessary information about this trial and provided a copy of the Informed Consent signed by the subject and the researcher

_____

Signature of the research leader

(indicate here the name and surname of the researcher, institution)