Effects of Transcutaneous Electrical Nerve Stimulation (TENS) on Postoperative Pain and Function Following Arthroscopic Knee Surgery: A Prospective Randomized Clinical Trial Pilot Study

Informed Consent
NCT01528228

Principal Investigator:

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CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES
A.T. STILL UNIVERSITY (ATSU) - KIRKSVILLE COLLEGE OF OSTEOPATHIC MEDICINE (KCOM) and NORTHEAST REGIONAL MEDICAL CENTER (NRMC)

Principal Investigator: Kevin Marberry, M.D., Associate Professor, Department of Surgery, ATSU-KCOM

1. You agree to participate in a research study at this institution. The title of the research is *Effects of Transcutaneous Electrical Nerve Stimulation (TENS) on Postoperative Pain and Function Following Arthroscopic Knee Surgery: A Prospective Randomized Clinical Trial Pilot Study*.

2. You understand that the purpose of the research is to determine the effectiveness of TENS therapy in the early postoperative period following knee arthroscopy (scope) for certain knee surgeries (meniscectomy, synovectomy, or chondroplasty). The goal is to enroll a total of 20 participants in this study. This pilot study will provide initial information for the effectiveness of the TENS device. The results of the pilot study will be used to design a larger multi-center prospective randomized clinical trial.

   Outpatient knee arthroscopy is a common procedure in the United States and pain is often controlled with medications. TENS has been offered to treat pain and therefore limiting narcotic pain medication use and medication side effects. This study will help us to better understand TENS and its' effect on the postoperative pain levels that patients have.

3. Your participation in this research study will last approximately 7 months and will involve completing questionnaires about your pain and abilities. You will complete daily pain assessments and reports of pain medicine use in the early postoperative period (first two weeks after surgery). You will complete 6-7 questionnaires about your pain and functional abilities at these times: preoperative and at 1, 2, 6, 12 weeks and 6 months postoperative. You understand that eligible participants will be randomly assigned into one of two groups – 1) Structured TENS therapy with a functioning device or 2) Placebo TENS therapy with a nonfunctioning device. The functioning TENS device will deliver a low level electrical impulse to the area around your knee. The non-functional unit is one that has been disabled and will not deliver an impulse to your knee. You and your surgeon will not be informed of which group you are in. TENS will be discontinued at two weeks postoperatively. You will be followed for a total of six months postoperatively with clinical measurements of muscle strength, knee range of motion, presence of joint fluid, and muscle size (measure of atrophy) assessed at each follow-up visit at 1 week, 2 weeks, 6 weeks, 12 weeks and 6 months. You agree that the researchers may use information from your clinic medical record. Information pertaining to the type of surgery and operative findings will be recorded.

Participant's Initials _____

4. You understand there are possible risks to you if you agree to participate in the study. They are the risk of loss of confidentiality related to the questionnaires if your information is obtained by someone other than the researchers. Precautions will be taken so that this does not happen. All data will be secured in a locked file located in a locked office in the Gutensohn Clinic.

   The TENS units are FDA (U.S. Food and Drug Administration) approved and safe and are used for this type of knee surgery at many hospitals in the United States. You understand that you will receive standard of care treatment regardless of your group assignment.

   You understand that if side effects or discomforts do occur, Dr. Kevin Marberry will try to minimize and treat these by standard measures as needed.

   You understand that the treatment or procedure described may involve risks to you which are currently unforeseeable.

   You understand that the researcher may terminate your participation without regard to your consent under certain circumstances or when, in the investigator's judgment, it is in your interest to do so.

5. You understand that the results of the research study may be published but that your name or identity will not be revealed and that your records will remain confidential. In order that confidentiality can be maintained, Dr. Kevin Marberry will assign a unique study number to each participant. The master list linking the number to the participants and all paper documents will be filed in a locked file cabinet that is stored in a locked office within the Gutensohn Clinic at ATSU. All information entered into a database will be done so using the assigned unique number and a secure password protected computer stored in a locked office or suite within the Gutensohn Clinic at ATSU. All discussions between the research team and participants will occur in a safe and secluded environment.

   You understand that your medical records and the records from this study may be reviewed by the research team, FDA and/or the sponsor, Don Joy (DJO, LLC).

   A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Once the study is completed, the Principal Investigator (Dr. Kevin Marberry) is responsible for destroying the link between the participants' personal health information and their unique study number. All de-identified research data will remain secured for a minimum of three years.

Participant's Initials _____ 6. You understand that your participation in this study may not benefit you directly. Possible benefits of your participation in the research study are the expectation that society may benefit from a significant contribution to medical knowledge. This knowledge of conditions, types of injuries, surgeries, complications and results may provide surgeons with research information that will help to establish a better understanding of the management and treatment of orthopaedic patients and will especially prove to be valuable as our population ages.

7. You understand that an alternative option is non-participation. You may decline to participate in this research study.

8. You also understand that your participation is voluntary and that refusal to participate will involve no penalty to you or loss of benefits to which you are otherwise entitled. You also understand that you may withdraw from the research study at any time without penalty or prejudice.

   You will be informed of any significant (major) new findings developed during the course of your participation in this research which may have a bearing on your willingness to continue in the study.

   As a voluntary participant in this research study, you understand that you will not be charged for the use of the TENS unit or for participation in this study. All standard charges for surgery will remain.

9. You will not be paid for participation in the research study.

10. You understand that there may be harm to an embryo or fetus if you should become pregnant. To the best of your knowledge, you are not pregnant, and if you do become pregnant, you will notify the researcher of your pregnancy.

11. To the best of your knowledge, you are not participating in any other medical research study.

12. Any questions that you may have concerning your participation in the research study will be answered by Dr. Kevin Marberry, Principal Investigator, who can be reached at 660.626.2663.

13. You understand that Dr. Kevin Marberry will evaluate and refer you for treatment in the event that an injury results because of your participation in this study. The

College/Medical Center has not set aside funds to provide financial compensation. The College/Medical Center assumes no liability for any injury that results from your participation in this project.

Participant's Initials _____

14. If you have any questions about your rights as a research subject or in the event you believe you have suffered any injury as a result of participation in the research study, you may contact, Robert Theobald, Ph.D., the Chairman of KCOM Institutional Review Board (6606262316), who will discuss your questions or will be able to refer you to the individual who will review the matter with you, identify other resources that may be available, and provide further information as to how to proceed.

15. I have read the above statements and have been able to ask questions and express concerns, which have been satisfactorily responded to by the investigator. I believe I understand the purpose of the study as well as the potential benefits and risks that are involved. I hereby give my informed and free consent to be a participant in this study.

_____ _____ _____ Date

Printed Name of Participant Signature of Participant

16. I certify that I have explained to the above individual the nature and purpose, the potential benefits and possible risks associated with participation in this research study, have answered any questions that have been raised, and have witnessed the above signature.

17. These elements of Informed Consent conform to the assurance given by KCOM to the DHHS to protect the rights of human subjects.

18. I have provided the participant a copy of this signed consent document.

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Date Signature of Investigator