Consent

Perineural Electrical Dry Needling Migraine Treatment Study

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RESEARCH INFORMED CONSENT INFORMATION
Agreement to be Part of a Research Study

Study Title: A Randomized Controlled Crossover study to Determine the Effectiveness of Peri-Neural Electrical Dry Needling (PNED) vs. Standard Care for the Treatment of Patients With Migraine Headaches.

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What should I know about a research study?

- This is a consent form for participation in a human research study.
- Taking part in this study is voluntary. You decide if you want to be in the study.
- You can choose to not be in the study. If you choose to be in the study, you may stop at any time. If you stop the study before it is finished, there will be no penalty to you and you will not lose any benefits that you could normally receive.
- No one can promise you that this study will help you.
- If you decide to be in the study, there may be extra risks or side effects.
- Someone will explain this research study to you. Make sure all of your questions are answered before you decide if you want to be in the study.
- If you join the study, you will be asked to sign this form and you will get a signed and dated copy of this form for your records.

Why is this study being done?

This study is being done to investigate a new treatment protocol utilizing electric stimulation of needles for patients with migraine headaches. The purpose of this study is to determine whether this new treatment protocol will benefit patients with migraine headaches. Use of the electrical stimulation unit is approved for how it will be used and is currently used in physical therapy clinics, however, this study seeks to determine if a certain protocol for use can benefit patients with migraine headaches.

Why am I being told about this study?

You have the option to be in this study because you have been treated for migraine headaches previously or are currently referred to this clinic for treatment of your migraine headaches.

About 30 people will take part in this research study at this location.

How long will I be in the study?

If you decide to participate you will be asked to be seen 2 days per week for 30 minutes over the course of 5 weeks. Data will be collected regarding pain ratings on a 0 to 10 scale and frequency of headaches, including use of a neck disability index survey. Data will both be collected via a survey given at each visit and also placed in your medical record as you will be a patient.

In addition to the time you are active in the study, we will collect information from your medical records for another year after your participation. You will be considered part of the study for a total of about 2 years.

What will happen if I take part in this study?

If you agree to be in this study, we will ask you to do the following:

Before you start the study

You will be asked to verify that: your age is at least 18 y/o, you have been diagnosed with or have symptoms of a migraine, your pain rating is appropriate for this study, and you do not have a history of epilepsy, are currently pregnant, have needle-phobia, have an unstable psychological status, have a compromised immune system, have a metallic allergy, and are unable to lie on your stomach or side.

During the study

This is a crossover study meaning that you will receive two forms of treatment, either standard care or standard care plus the investigational treatment.
Standard care will include the following: cervical or thoracic joint manipulation or mobilization, a therapeutic exercise program consisting of strengthening or stretching exercises, trigger point electrical dry needling and soft tissue manipulation.

The procedures involved in the investigational care will involve use of electrical dry needling using a certain electrical frequency and specific placement of the needles. The procedures are being tested in this study to see how it affects your body and migraine headaches.

When you are done with the study intervention

After you are finished with the 5 week phase of the study, you may continue to receive treatment as a patient based on your current medical need.

What risks, side effects or discomforts can I expect from being in the study?

You might have risks, side effects or discomforts if you take part in this study that you may not have if you are not in the study.

The study treatment can cause side effects. Everyone taking part in the study will be watched carefully for any side effects. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop receiving treatment. In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death.

Most Common Side Effects or Discomforts are:
Muscle soreness, bruising, increased head or neck pain.

Because this research study involves an experimental protocol we do not know all of the possible harms or risks. There may be other risks related to your participation in this study such as neurological symptoms including numbness and tingling.

Talk to your study doctor about any side effects that you have while taking part in the study.

Breach of Privacy and Confidentiality
As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure your personal information to ensure confidentiality. This is described in more detail later in this form.

Will my study-related information be kept private?

If you sign this consent form, you are giving permission to let the Investigator and study staff use and share your information for the purpose of this study.

In general, the records of the study will be kept private. There are some cases where we may share your information. For example, your records may be reviewed by Ascension Wisconsin employees or agents, study sponsors or monitors, or government agencies (U.S. or foreign) that conduct the study or have to make sure that the study is being done safely and correctly. You will not be identified in any articles or presentations about this study.

There may be certain times when the study doctor and research team may have to share or report information learned during this study, these include the following:

- If the study staff finds evidence of abuse or neglect, researchers may be required by law to report this to local law authorities.

Medical Records and Health Information
Federal law provides additional protections of your medical records and related health information. These are described in a different form.

What benefits can I expect from being in the study?

Being in this study might benefit you by reducing the intensity (how bad) and/ or frequency (how often) of your migraine headaches.

We hope to use the information we get from this study to further knowledge about treating migraines.

Will it cost anything to be in the study?

There are no additional costs to you if you participate in this study. If you are a patient being treated your insurance company may be billed for Physical Therapy care (care you would receive as a patient if you were not in this study)

If you have questions about study costs, you can talk to the Investigator or study team.

What happens if I am injured because I took part in this study?

If you are injured as a result of being in this study, you should contact the study doctor as soon as possible. Treatment will be available, including first aid, emergency treatment and follow-up care as needed. You or your insurance will be billed for the cost of this treatment.
There is no compensation or pay offered for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study.

If you think you have suffered a study injury, let the study doctor know right away. You are not giving up any of your legal rights by signing this consent form.

Will I be paid for taking part in this study?

You will not be paid for being in this research study.

Will I be told about the results of this research?

If we learn new things during the study that may affect you or your willingness to continue in the study, we will tell you as soon as possible. After the study has been completed, we will notify you of the results.

Can I stop being in this study? What are my rights?

You don't have to be in this study. If you do choose to be in the study, you are free to partially or completely end your participation in the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will

not affect your relationship with Ascension Wisconsin or any location owned or operated by Ascension Wisconsin. If you are an employee, your decision will not affect your employment status.

After you leave the study, no new information will be collected from you. Information that has already been collected will remain in the study database and be used to determine the results of the study.

In addition, the study doctor could end your participation in this study if they don't feel that it is in your best interest, if the study is stopped early, or if the PI determines that you have been non-compliant with the study protocol.

What other choices do I have if I do not take part in the study?

If you choose not to be in this study, you can still get any treatments normally available as standard care in the clinic.

The study doctor will discuss these with you. You do not have to be in this study to be treated for migraine headaches.

Who can answer my questions?

You should contact the research team if you have any questions about the study, concerns, complaints, or if you think you have been hurt by the study.

You can contact them at:
Joe Tepp DPT ; phone number:(414) 389-3023; email: joseph.tepp@ascension.org
Sara Kotchi, DPT; phone number: (414) 647-3920; email: sara.kotchi@ascension.org

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You can contact them at: at 414-465-3134 or IRB@ascension.org. You can contact them if:

- You have questions about your rights as a research subject.
- Your study questions, concerns or complaints are not being answered by the research team.
- You can't get a hold of the research team or if you want to talk to someone else.

Statement of Consent

I have read the information above. I have asked questions and received answers. I consent to be in the study.

_____

Print name of subject

_____

Signature of subject Date

Person Obtaining Informed Consent

_____

Print name and title of person obtaining consent

_____

Signature of person obtaining consent Date