

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Study to evaluate the safety, efficacy and tolerance of intense therapeutic ultrasound (ITU) for the treatment of lateral epicondylitis.

PROTOCOL NO.: 20150654 **DATE:** March 2, 2015

SPONSOR: Guided Therapy Systems

INVESTIGATOR: John Kearney, M.D.

**STUDY-RELATED
PHONE NUMBER(S):** John Kearney, M.D.
623-537-5600 (24 Hours)

**STUDY
COORDINATOR(S):** Beth Gleason, MA
623-537-5695

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- Other parts of this study may involve procedures that are being tested for a certain the treatment of epicondylitis.
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.

- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed then it may have access to the research records.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY

- The research is being done to investigate the effect of ultrasound therapy on tendinosis of the **Common Extensor Tendon (CET)**. This condition is also sometimes referred to as “tennis elbow”.
- The experimental component of this study is the use of **Intense Therapeutic Ultrasound (ITU)** to treat “tennis elbow”. ITU is a more focused, higher energy form of the ultrasound technique that is already used to observe soft tissues of the musculoskeletal system.

PROCEDURES

- The experimental procedure that you will receive will involve a 20 minute session of ITU application. During this procedure you will be lying on your stomach with the option of supporting your legs with a pillow. You will also be administered questionnaires to assess your levels of pain, function, and physical activity. Diagnostic Ultrasound Imaging will be used to determine the thickness of your CET.
- The ITU application will be a part of the experimental procedure. The questionnaires and the Diagnostic Ultrasound Imaging will be used to assess the effect of the ITU.
- If you consent to participate in this study, then you will be placed in the treatment group and will receive ITU as treatment for your “tennis elbow”.
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RISKS AND DISCOMFORTS

- Temporary reddening of the skin (for less than 24 hours) or mild-moderate tingling, warming, or pain associated with the ITU application.
- Error in application that leaves you with a burn on the application site. Additionally, in rare cases you will have reddening of the skin at the application site, or mild-moderate warming, tingling, or pain at the application site lasting more than 24 hours.

There may be side effects that are not known at this time.

Women who are pregnant, nursing a child, or were pregnant within the last three months may not take part in this study. If you think that you have gotten pregnant during the study, you must tell your study doctor immediately. Pregnant women will be taken out of the study.

Other Risks

Your condition may not get better or may get worse during this study.

NEW INFORMATION

You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS

Your “tennis elbow” may improve while you are in this study; however, this cannot be promised. The results of this study may help people with “tennis elbow” in the future.

COSTS

Guided Therapy Systems will provide ITU application free of charge during this study. Tests and procedures that are done only for the study will not be billed to you or your insurance company.

You or your insurance company may be billed for:

- Any standard medical care given during this research study.
- Including any complications associated with the procedure, and the standard physical therapy.

You may want to talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay, you may be billed for those charges.

You might have unexpected expenses from being in this study. Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

PAYMENT FOR PARTICIPATION

Complete follow-up is very important to the outcome of the study. You will be paid \$25.00 each for visits completed within the required window dates for the week: 0, 2, 4, 8, & 24. You will not be paid for day 0 or week 12 telephone call. You will be paid in the form of cash, check, or cash card after the visit to offset the cost of meals, transportation, and parking. If the visit is completed outside the window dates (either early or late), you will not be eligible for the payment, but would continue to be eligible for payment for any future visits if the visit is completed within the window date. No payment will be provided for missed follow-up visits, or visits not required by the study plan. If you do not complete the study, you will be paid for any of the listed visits you do complete.

ALTERNATIVE TREATMENT

If you decide not to enter this study, there are other choices available. These include: rest, stretching and strength training, or OTC painkillers. Ask the study doctor to discuss these alternatives with you. You do not need to be in this study to receive treatment for your condition.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?

The study doctor and the study staff. They may also share the research information with Guided Therapy System.

Who might get this information?

The sponsor of this research. “Sponsor” means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information may be given to:

- Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission.

COMPENSATION FOR INJURY

If you are injured or get sick as a direct result of being in this study, call the study doctor immediately. The study doctor will provide treatment. Your insurance will be billed for this treatment. No other payment is routinely available from the study doctor or sponsor.

If you believe you have been injured from participating in this research you may contact the study doctor.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is completely voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

It is not possible to completely eliminate the risk of a fall while performing the exercises. If you suffer a fall as a direct result of your performance of the exercise program, contact the study doctor immediately so we can assess your continued participation in this study.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- if it is decided to be in your best interest;
- if you do not consent to continue in the study after being told of changes in the research that may affect you;
- if you do not complete the exercise program but do not notify the research personnel or doctor that you have chosen to not participate in the experimental program.

SOURCE OF FUNDING FOR THE STUDY

The sponsor Guided Therapy Systems will pay for this research study.

QUESTIONS

- Contact Dr. Kearney at The CORE Institute at 623-537-5600 (24 hours) if you feel you have had a research-related injury.
- if you have any questions about your participation in this study,
- if you have questions, concerns or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

Subject Name (printed)

Signature of Subject

Date