Using Inflammatory Biomarkers and EMO results to Predict Epidural Injection Response in Patients Diagnosed with Lumbar Stenosis

Clinical Study Protocol

NTC Number: 03511053

Principal Investigator: Thiru Annaswamy, M.D.
VA North Texas Healthcare System
4500 S Lancaster Road
Dallas, TX 75216
214-857-0273

09 March 2018

Subject Name: _____ Date: _____

Title of Study: Using Inflammatory Biomarkers and EMG results to Predict Epidural Injection Response in Patients Diagnosed with Lumbar Stenosis

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Study Coordinator: Mitchell Kroll

Aleksander Borresen, Chung-Kuang Lin

Before agreeing to take part in this research study, it is important that you read and understand the proposed research explained below. It describes the procedures, benefits, risks and discomforts of the study. It also describes other treatments that are open to you and your right to withdraw from the study at any time. It is important for you to understand that no promises can be made about the results of the study.

A description of this clinical trial will be available on *http://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.

1. WHAT IS THIS RESEARCH STUDY ABOUT?

The purpose of this research is to find out if there are inflammatory biomarkers (also known as biological markers) in epidural space that can predict response to an epidural steroid injection. We are also evaluating whether the results of an EMG study (also known as electromyography) can predict the response to an epidural steroid injection as well.

The expected duration of your participation is approximately 3 months.

The approximate number of research subjects involved in this study is 10. 5 subjects will be enrolled at the VA North Texas Health Care System.

2. WHAT WILL HAPPEN DURING THE STUDY?

If you volunteer to take part in this research study, you will be asked to sign this consent form and will have the following tests and procedures. Some of the procedures may be part of your standard medical care, but others are being done solely for this study.

Screening Procedures

SUBJECTS IDENTIFICATION (last name, first, middle and full SSN)

To help decide if you qualify to be in this study, the researchers will ask you questions about your health, including medications you take and any surgical procedures you have had.

You will also have to fill out certain forms.

- Form 1: Pain Disability Questionnaire

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- Form 2: Swiss Spinal Stenosis Questionnaire
- Form 3: Visual Analog Scale for Back and Leg Pain

Study Intervention

If you decide to participate in this study you will:

- Complete a series of questionnaires relating to your pain and activities of daily living
- Blood tests
- Immediately prior to your lumbar epidural steroid injection, your physician will perform an epidural lavage by injecting a small amount of saline (salt water) into the epidural space, and withdrawing the fluid soon afterward. This epidural fluid that is withdrawn will be sent to a special laboratory at UT Southwestern Medical Center for biomarker analysis.

Procedures and Evaluations during the Research

You will not have any study related visits outside your regular clinic visits. However, some of the visits may last around 30-45 minutes longer than normal, due to the time it takes to complete the study related questionnaires.

Visit 1 (Baseline):

- You will complete three questionnaires
- Venipuncture for blood tests
- You will undergo the EMG test, which is a standard diagnostic test done to look for any injury or damage in your nerves or muscles. Risks associated with this procedure are described below.
- You will undergo an epidural lavage, as described above. Risks associated with this procedure are described below.

Visit 2 (1 month after scheduled procedure):

- You will complete three questionnaires

Visit 3 (2 months after scheduled procedure):

- You will complete three questionnaires

Procedures for storing extra or left over samples

Samples will be stored until all patients are enrolled and their procedures are completed. You will be identified by a numerical code during gathering and reporting of data. All samples from the enrolled patients will be tested at the same time. Once samples are tested, your blood and lavage

samples will be stored at the Dallas VA until the completion of the study, in case additional biomarker tests need to be performed. Upon completion of the study, all samples will be destroyed.

The questionnaires and procedures used in this study are designed for research, not for medical purposes. They are not useful for finding problems or diseases. Even though the researchers are not looking at your results to find or treat a medical problem, you will be told if they notice something unusual. You and your regular doctor can decide together whether to follow up with more tests or treatment. Because the questionnaires and biomarkers done in this study are not for medical purposes, the research results will not be sent to you or to your regular doctor.

3. WHAT ARE MY RISKS?

Because of your participation in this study, you are at risk for the following side effects. Most of these are usual risks associated with routine medical care (Electromyography and Epidural Steroid Injections). Additional risks due to your participation in this study are listed below. You should discuss these with the researchers and your regular health care provider.

Electromyography:
No serious complications are expected with this standard clinical procedure or test. You may have some minor aches or pains or minimal bleeding where the needle was placed, but this should go away.

Epidural Steroid Injections:
Complication rates from epidural steroid injection vary from 1% to 3%. Serious and rare complications associated with epidural steroid injection are infrequent.

Rare complications include temporary or permanent paralysis (nerve damage), infection, bleeding or injury to blood vessel, stroke, allergic reaction to injected materials, potential need for immediate surgery, clotting of veins, loss of limbs, and death.

Infrequent complications may include increased pain or numbness in the legs, bleeding at the injection site, a dural tear (tear in the outer sac around the spinal cord) causing leakage of spinal fluid and a headache, facial flushing, allergic reaction and elevations of blood sugar levels in persons with diabetes.

Potential adverse events following prolonged fluoroscopy (X-ray) include: hair loss, skin redness, and skin damage.

Epidural Lavage:

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During the lavage process, you may feel a slight pressure sensation or mild discomfort at the level of your epidural steroid injection.

Fluoroscopy:
All human beings are constantly being exposed to naturally occurring background radiation. This procedure(s) will expose you to about 6 months of natural background radiation exposure. No increased risk has been scientifically demonstrated from this level of exposure, though a very small increase in cancer risk may exist

Venipuncture/Blood Draw:
Risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, and/or fainting are also possible, although unlikely. You will have approximately 2 tablespoons of blood drawn for research purposes.

Psychological Stress:
Some of the questions related to the study may make you feel uncomfortable. You may refuse to answer any of the questions or take a break or stop participation in the study at any time.

Loss of Confidentiality:
Any time information is collected; there is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential and secure. However, this cannot be guaranteed.

Unforeseen risks: A previously unknown problem could result from your taking part in this research. There could be an interaction between the study drug and other medications you take (prescribed or over-the-counter). It is not possible to estimate the chances of such problems or how serious the problems could be. Any new findings will be given to you that may affect your willingness to take part in this study. If new findings are discovered, you will be asked to sign a new (updated) informed consent form to document that new information provided in the updated Consent Form has been explained to you.

4. WILL THE RESEARCH BENEFIT ME OR OTHERS?

If you agree to take part in this study, there may not be direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this research.

We hope the information learned from this study will benefit others with lumbar stenosis in the future. Information gained from this research could lead to better understanding regarding which patients will benefit from injections.

5. WHAT ARE MY ALTERNATIVES TO BEING A RESEARCH SUBJECT?

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You do not have to be in this study to receive treatment for your condition. Your other choices may include bed rest, pain management with oral medications, changing your activity, physical therapy, invasive spine surgery, or injection of pain medication (not in the study). You should talk to the researcher and your regular physician about each of your choices before you decide if you will take part in this study.

6. WILL I GET PAID?

Yes. You will be paid $25.00 at the end of the study. If you stop taking part in this study or are withdrawn by the research team, you will not receive any payments.

Your Name, Address, and Social Security Number must be disclosed to UT Southwestern Medical School employees in order to process any payments to you.

7. WILL I HAVE TO PAY?

Subjects do not pay for treatment associated with participation in a VA research program. You will be responsible for any co-payments that would be normally required of you to receive care at the VA, when you come in for the EMG test or the ESI procedure.

8. DOES BEING PREGNANT OR THE POSSIBILITY OF BEING PREGNANT PREVENT ME FROM TAKING PART?

Every effort will be made to have females enter this study on an equal basis with male subjects. Medically accepted birth control is needed to enter this study. This includes, but is not limited to: abstinence, birth control pills, IUD's, condoms, diaphragms, implants, being surgically sterile, or being in a post-menopausal state. However, no birth control method completely prevents pregnancy. If you become pregnant there may be a high risk of miscarriage, birth defects or other problem for the fetus. If you are female and of child bearing age, you must have a negative pregnancy test before starting the study.

If you are or become pregnant, the study related treatment or procedure could involves risks to your unborn child which are currently unforeseeable and unknown.

9. WHAT IF I GET INJURED?

The VA has the obligation to provide medical treatment to participants injured by participation in a VA study. If you are injured as a result of being in this study, the VA will provide medical treatment in accordance with federal law.

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10. ARE MY RESEARCH RECORDS SAFE FROM THE PUBLIC?

The study doctors keep your research records private in the same way as your other medical records. No one has access to your records except as required by law. You are, however, authorizing UT Southwestern Medical Center, the Dallas VA Institutional Review Board (IRB), the Dallas VA Research and Development Committee and the members of the Dallas VA Research Office to inspect your medical and research records. These committees, people, and offices at the Dallas VAMC are responsible for overseeing human research studies.

If you choose to take part in the study, certain government agencies (such as the FDA or VA) may look at your research records. Your name as a subject in this study is private, and will not be included in any report prepared as a result of this study.

11. DO I HAVE TO TAKE PART IN THIS STUDY, OR CAN I WITHDRAW FROM THE STUDY?

Taking part in this study is voluntary and you may refuse to take part without penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw your consent and stop taking part at any time. Not taking part in the study will in no way affect the quality of care you receive now or in the future from the VA. This will also not affect your right to take part in other studies. The study doctors will answer any questions you may have about the study.

Your doctor may also take you out of the study without your consent for medical or administrative reasons. Any significant new findings that develop during the course of the research study that the study doctor thinks may affect your willingness to continue to take part will be given to you as soon as possible.

12. WHOM SHOULD I CONTACT FOR QUESTIONS OR PROBLEMS?

If you have any questions about this study or have any bad effects of your treatment, you should call the study doctor at 214-857-0273 or a member of the research team at 214-857-1544. You should also contact the study doctor or a member of the research team to discuss problems, concerns you may presently have, or offer input about the research.

If you have any questions about whether this is a VA North Texas Healthcare System-approved research study, you may contact the Research Compliance Officer at 214-857-0341.

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If you have any questions about your rights as a patient, complaints about your treatment or general concerns about the conduct of the research study, of if you have questions, complains, concerns you may contact the Dallas VAMC Patient Representatives at 214-857-0482. The Patient Representative will guide you in resolving your question or complaint.

If you have a medical emergency you should immediately call 911 for assistance.

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RESEARCH SUBJECT'S RIGHTS:

I have read or have had read to me all of the above. The study has been explained to me and all of my questions have been answered. If I have questions later, it has been explained to me that I can contact Dr. Annaswamy. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment open to me.

It has been explained to me that I do not have to take part in this study and my refusal to take part will involve no penalty or loss of rights to which I am entitled. I may withdraw at any time without penalty or loss of VA or other benefits to which I am entitled. The study doctor can take me out of the study at any time if it appears to be medically harmful to me, if I fail to follow directions for taking part in this study, if it is discovered that I do not meet the study requirements, or if the study is canceled.

In case there are medical problems or questions, I have been told I can call Dr. Annaswamy at 214-857-0273 during the day or at 800-725-4436 after hours.

I was informed of my rights as a research subject, and I voluntarily consent to take part in this study. I authorize the use of my identifiable patient health information as described in this form. I will receive a signed copy of this consent form.

_____ _____

Participant's Signature Date

_____ _____ _____

Name of person obtaining consent Signature of person obtaining consent Date

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Research Subject's Bill of Rights

1. Be informed of the nature and purpose of the research.

2. Be clearly told of the procedures to be followed in the medical research, and any drug or device to be used.

3. Be clearly told of any discomforts and risks that might be expected from the research.

4. Be clearly told of any benefits that the patient might expect from the research.

5. Be clearly told of any other appropriate procedures, drugs, or devices that might be helpful to the patient, and their risks and benefits.

6. Be clearly told how to get medical treatment, if needed, after the research is finished if problems should arise.

7. Be given the chance to ask any questions about the research or the procedures involved.

8. Be clearly told that consent to take part in the medical research and/or release of identifiable patient health information may be taken back at any time. The patient may stop taking part in the medical research without any penalty or loss of VA or other benefits.

9. Be given a copy of the signed and dated written consent form.

10. Be given the chance to decide to consent or not to consent to a medical research study without any force, fraud, deceit, duress, coercion, or undue influence on the patient's decision.