

**COMPOUND AUTHORIZATION AND CONSENT
FOR PARTICIPATION IN A RESEARCH PROJECT
YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL**

Department: Yale-New Haven Hospital Spine Center

Principal Investigator: Dr. Robin Raju, MD **Telephone:** 203-688-8800

Medical Study Title: Comparison of pain perception and incidence of intravascular injection during transforaminal epidural steroid injection (TFESI) using 22 gauge vs 25 gauge needle

Lay Study Title: A research study to evaluate whether there is any difference between needle sizes when used for spine injections.

You are invited to take part in a research study designed to compare needle size during epidural steroid injection. You have been asked to take part because you have already been diagnosed with a pinched nerve in the back and have consented to transforaminal epidural injection as part of your standard of care clinical treatment.

As required by federal regulations, this research study has been reviewed and approved by an Institutional Review Board (IRB), a University committee that reviews, approves and monitors research involving humans.

What Is Informed Consent?

Before a knowledgeable decision about whether to participate in a research study can be made, the possible risks and benefits related to the study should be understood. This process of learning and thinking about a study before deciding to participate is known as *informed consent* and includes:

- # Receiving detailed information about this research study;
- # Being asked to read, sign and date this consent form once the nature of the study is understood and a decision is made to participate. If there is anything about the study you don't understand or if there are questions, you should ask for explanations before signing this form;
- # Being given a copy of the signed and dated consent form to keep.

What is the purpose of this study?

The purpose of this study is to evaluate incidence of vascular uptake during epidural injection when using 2 different kinds of needles. Although extremely rare, serious complications have been reported in literature with epidural injections including spinal cord injury, bleeding and paralysis. Some researchers think it's due to the steroid medication getting into blood stream. We are looking to see if using a specific kind of needle can decrease the amount of steroid getting into blood stream, hence reduce the overall risk associated with epidural injection. We will be studying 2 different kinds of needles – 22 gauge needle and 25 gauge needle. We want to see if 25 gauge needle will result in less steroid uptake into the blood stream. Physicians use both kinds of needles currently in practice but there has never been a study to see which one is better.

How many individuals will participate in the study and how long will the study last?

250 patients will participate in this study. Patients will be enrolled at Yale University, from the Yale-New Haven Hospital Spine Center. You will be given a questionnaire before and after the

injection to rate your pain. Each participant will be in the study for about 30 days. You may receive a phone call 30-days after your injection to collect any complications following your injection, if you haven't followed up with your physician by then.

What will happen during the study?

If you agree to participate in this study and sign this informed consent document, your injection will be done by either a 22 gauge or a 25 gauge needle. The size of the needle will be randomly assigned by a computer and will not be known beforehand by your physician. You will not be told which size needle will be used for this injection. Before and following your injection, we will ask you to complete a pain questionnaire which will ask you to rate your level of pain on a 0-10 scale.

Research staff will collect information from your medical chart regarding details of your injection procedure, and for 30 days following your injection to collect information regarding any complications following your injection. If you haven't followed up with your doctor within 30 days, we may give you a call to inquire any complications.

What are the side effects and other risks or discomforts involved?

Patients who elect to be in this study have already been diagnosed with pinched nerve in the back and this study doesn't affect the treatment of this condition. Patients in this study also have agreed to get epidural injection, and risks associated with this procedure not different, increased or decreased, by being in this study. We are predicting that there may be increased risk for blood stream uptake of steroid particles with 22 gauge needle as opposed to 25 gauge needle. As mentioned earlier, this phenomenon has not been shown in any studies yet to date. The only other risks/discomforts are lost time from filling out the questionnaires/consent forms.

Tell the study doctor or research team as soon as possible if any of the side effects, risks or discomforts listed below occur or if you think a side effect that is not listed may be happening.

If your condition worsens, if side effects become very severe, or if it turns out that being in this study is not in your best interest, you will be taken out of the study.

If questions come up about side effects, ask the study doctor or staff at any time during or after the study.

Common, some may be serious, could happen in 20% or more of subjects

-Numbness to legs

-Temporary increase in pain due to body's reaction to steroid

Occasional, some may be serious, could happen in 3-20% of subjects

-Dizziness

-Allergic reactions

Rare and serious, possible in up to 3% of subjects

-Paralysis

There may be additional risks related to this study that are not yet known.

What are the risks to fetuses, infants and pregnant women?

Pregnant women or women who are breast feeding will not be enrolled in this study. To be in this study you and your partner must practice adequate birth control measures. The study doctor will discuss acceptable methods of birth control with you. If you are a woman of childbearing potential, you will have a pregnancy test before making a decision about being in this study. The results of this pregnancy test will be made available to you prior to the start of the study.

Are there benefits from being in this study?

There is no direct benefit to you from being in this research study, but we hope that what we learn may be helpful to future patients or society in general.

Are there alternatives to being in the study?

Participation in this study is entirely voluntary. This study does not provide treatment and the alternative is to not participate and have your procedure with the practitioner choosing the needle size to use.

How will privacy and confidentiality (identity) be protected?

Information about your study participation will be entered into your Electronic Medical Record (EMR). Once placed in your EMR, these results are accessible to all of your providers who participate in the EMR system. Information within your EMR may also be shared with others who are appropriate to have access to your EMR (e.g. health insurance company, disability provider).

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as permitted by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. All study-related data will be coded and stored in locked cabinets or on computers that are password protected. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name, address, date of birth and other identifying information. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. All study-related data will be coded and stored in locked cabinets or on computers that are password protected. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be destroyed after the completion of data analysis..

The information about your health that will be collected in this study includes:

- o Medical Diagnosis*

- o Pain Questionnaire*
- o Any complications after the procedure*
- o Medical History as it relates to study participation*

Information about you and your health which might identify you may be used by or given to

- # Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- # Those providers who are participants in the Electronic Medical Record (EMR) system.
- # Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- # The Principal Investigator, Dr. Robin Raju
- # Co-Investigators and other investigators
- # Study Coordinator and Members of the Research Team
- # Any person or agency required by law

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine and Yale-New Haven Hospital, are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies. However, by deciding to take part in a blinded treatment study and sign this consent, you will not be allowed to look at or copy your study related information until after the research is completed.

If you develop an illness or injury during the course of participation in this study, other PHI about treating and following the condition may be generated and disclosed as it relates to this study.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing, Dr. Robin Raju, Yale-New Haven Hospital Spine Center, 1 Long Wharf Drive-6th Floor, New Haven, CT 06511. If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

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.

What happens in case of injury as a result of being in this study?

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.

Yale School of Medicine and Yale-New Haven Hospital do not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

Is there payment for being in this study?

There is no payment for participating in this study.

Are there costs related to being in this study?

Research Procedures

There are no charges to you or your insurance carrier for study visits or tests that are part of this research.

Standard Testing Procedures

Standard of care procedures and doctor visits will be billed to your health insurance carrier. These are charges that would be billed to insurance whether in a research study or not. It is possible that insurance coverage may be denied. If that happens you may be responsible for some or all of these charges.

In addition, if your health insurance carrier is charged, you will be responsible for out-of-pocket costs for standard of care procedures, including co-payments and deductibles.

The study doctor [or study staff] will explain which procedures, tests and doctor visits are considered standard of care. You should check with your health insurance carrier to be sure you understand what costs you may be responsible for paying.

If a bill is received that you think is wrong, please discuss it with the study doctor or research coordinator.

What if the research results in new findings?

Anything learned during the study, beneficial or not, that may affect your health or willingness to continue in the study, will be explained.

Can I be removed from the study or quit the study?

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

Withdrawing From the Study

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. The researchers may withdraw you from participating in the research if necessary.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with *Yale-New Haven Hospital*.

Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to Dr. Robin Raju at 1 Long Wharf Drive-6th Floor, New Haven, CT 06511.

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 until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

CONTACT INFORMATION

If you are having a medical emergency, call 911 or go directly to an emergency room. You should let emergency personnel or providers know that you are participating in this study.

If you have any questions about the research or develop a research-related problem, you should contact the study doctor, Dr. Robin Raju at (203) 688-8800. If you have any questions about your rights as a research subject, you should contact the Yale Human Investigation Committee at (203) 785-4688.

Subject Communications

Do you wish to communicate with the study staff by e-mail? YES _____ NO _____

If you checked yes, please print your e-mail address on the line below.

RISKS: Steps are taken to protect your confidentiality when sending information by e-mail. However, e-mail is not always secure. There is always the risk that personal information sent by email could be seen by someone other than you.

YOU SHOULD NEVER USE E-MAIL TO REPORT A SUSPECTED ADVERSE EVENT OR ANY OTHER MEDICAL PROBLEM. THESE SHOULD BE REPORTED BY TELEPHONE.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject: _____

Signature: _____ Date: _____

Signature of Principal Investigator Date
or

Signature of Person Obtaining Consent Date

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator Dr. Robin Raju at (203) 688-8800. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.