Virtual Reality as a Substitute for Procedural Sedation During Epidural Steroid Injections

NCT04887285

3/15/2022

INFORMED CONSENT FORM
The Johns Hopkins University

Title of Project: Can a Virtual Reality Modality Substitute for Procedural Sedation and Improve Tolerance in Patients Receiving Epidural Steroid Injection for Pain? A Randomized Controlled Trial.

Principal Investigator: Steven Cohen, MD

Sponsor: Department of Defense (DoD) Defense Health Agency (DHA) through the Uniformed Services University (USU)

Participant's Printed Name: _____

INTRODUCTORY PARAGRAPH

Taking part in this study is entirely voluntary. We urge you discuss any questions about this study with our staff members. Talk to your family and friends about it and take your time to make your decision. If you decide to participate, you must sign this form to show that you want to take part.

This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study, this informed consent form includes two parts. The first part of this document includes information that applies to all study sites. The second part of the consent form includes information specific to the study site where you are being asked to enroll.

Research Summary

You are being asked to take part in a research study. Your participation in this study is voluntary. You are being asked to participate in this study because you are receiving a lumbar epidural steroid injection for your lower back pain as part of your standard clinical care. If you agree to participate in this study, on the day you are to receive your epidural steroid injection we will ask you some questions about you pain. We will also ask you questions about any conditions that may affect your pain. This should take about 10 minutes. We will ask what medications you take for your pain. We will then randomize you (like drawing numbers from a hat) into one of three groups. Group A will receive the sedation medications fentanyl and midazolam during the epidural steroid injection. Sedation medication is a type of relaxing medication. Group B will receive virtual reality equipment to wear during the epidural steroid injection. The virtual reality equipment will provide images that may distract you during the epidural steroid injection. You will be given a choice of three virtual reality programs to use during your epidural steroid injection. Prior to your epidural steroid injection, a study team member will demonstrate to you how to use the virtual reality equipment. A study team member will than answer any questions you may have. You will wear this equipment and use it during your epidural steroid injection. Group C will not receive sedation medication or virtual reality equipment to wear. All three groups will receive a local pain medicine call lidocaine that will be injected into the skin prior to the start of the epidural steroid injection procedure.

Immediately after you receive your lumbar epidural steroid injection we will ask you questions about the pain related to the procedure. We will also ask you to fill out some questionnaires that ask you about your feelings toward the procedure you received. When you return for your standard of care follow-up visit in about a month we will ask you more questions about you pain. We will also ask you to fill out two questionnaires. This will take about 15 minutes total. Once you have completed this visit you will have completed the study. There are some risks to the study drugs and procedures which are discussed later in this form. You may or may not benefit from taking part, and there is no cost to you to join.

Section 1. PURPOSE OF THE RESEARCH

You are being offered the opportunity to take part in this research study you are receiving a lumbar epidural steroid injection for your back pain. This research study is being done to find out what is the most effective way to make patients comfortable while they are undergoing their lumbar epidural steroid injections. Approximately 126 people will take part in this study across all study sites.

Section 2. PROCEDURES

Screening
We will first need to confirm that you are eligible for the study. Your physician will determine if you are eligible for this study during based on your medical history and the type of treatment recommended for you.

Baseline Data Collection and Randomization
If you are eligible for this study and agree to participate, you will be randomized (like drawing numbers from a hat) to one of three study groups:

- Group A will receive sedation medication during the epidural steroid injection. Sedation medication is a type of relaxing medication.
- Group B will receive virtual reality equipment to wear during the epidural steroid injection. The virtual reality equipment will provide images that may distract you during the epidural steroid injection.
- Group C will not receive sedation medication or virtual reality equipment during the epidural steroid injection.

All three methods are normally used in regular clinical practice. All groups will receive a local anesthetic prior to the epidural steroid injection. Your chances of being assigned to groups A, B, and C are equal.

We will need to collect some information from you prior to your lumbar epidural steroid injection. We will collect your demographics (including age, gender, and race/ethnicity, etc.), how long you've had lower back pain, what caused your pain, how severe your pain is on a 0-10 scale, your medical history and the medications you're taking. Once we collect this information you will receive your study intervention and your lumbar epidural steroid injection.

If you are randomized to group A, you will receive sedation and pain medications through an intravenous catheter prior to the start of your epidural steroid injection. The medications that you will receive are midazolam, a sedative, and fentanyl, an opioid pain reliever. You will also receive a local anesthetic pain medication called lidocaine injected into the skin area where your procedure will occur. Once you have received these medications your epidural steroid injection will begin.

If you are randomized to group B, about 15 minutes prior to the start of your epidural steroid injection, a study team member will explain the virtual reality environments available to you and provide a short demonstration. You will then choose one of the virtual reality environments and a study team member will demonstrate to you how to use the equipment in the environment that you have chosen. Once the demonstration is complete, you can ask any questions you have about the use of the equipment. After you are positioned for your procedure in the procedure room, you can start to use the virtual reality program. Similar to group A, you will also receive a local anesthetic pain medication called lidocaine injected into the skin where the epidural needle will be placed. Your epidural steroid injection procedure will then begin. You will wear the virtual reality equipment until the procedure is complete and remove the equipment prior to leaving the procedure room.

If you are randomized to group C, once you are positioned for your procedure you will also receive lidocaine injected into the area where the epidural will be done. Your epidural steroid injection procedure will then begin.

Immediately after you receive your lumbar epidural steroid injection we will ask you questions about the pain related to the procedure. We will also ask you to fill out some questionnaires that ask you about your feelings toward the procedure you received.

When you return for your standard of care follow-up visit in about a month we will ask you more questions about your pain. We will also ask you to fill out two questionnaires. This will take about 15 minutes total. Once you have completed this visit you will have completed the study.

Schedule of activities

Procedures	**Screening (during regular clinic visit)**	**Day of Lumbar Epidural Steroid Injection**	**Follow-up Visit**
Informed Consent		X	
Demographics/Medical History		X	
Data Collection		X	X
Review of Medications		X	
Randomization		X	
Administer Study Intervention		X	
Complications			X
Complete Case Report Forms		X	X

Section 3. TIME DURATON OF THE PROCEDURES AND STUDY

If you agree to take part in this study, you will be in this study 24 to 40 days. You will have two visits to the pain clinic. Each clinic visit will take approximately 1 hour.

Section 4. DISCOMFORTS AND RISKS

While on the study, you are at risk for the following side effects. Most of them are listed below but they will vary from person to person. If you experience any side effects, your doctor will administer treatment. Many side effects go away after the drug or procedure is stopped but, in some cases, the side effects may be serious and/or lasting.

Sedation/Pain Medication

More likely
- Nausea/Vomiting

Less likely
- Decreased breathing rate (very rare in the doses used in this study, <1 in 10,000)
- Decreased cardiac output (very rare in the doses used in this study, <1 in 10,000)

Virtual Reality

More likely
- Vertigo
- Nausea/vomiting
- Discomfort

Other Possible Risks Associated With Participating in This Study

- **Venipuncture:** The risks of placing and intravenous catheter for medication administration include temporary discomfort from the needle stick, bruising, bleeding, and, rarely, infection.

Section 5. POTENTIAL BENEFITS

Possible Benefits to the Participant
The possible benefit you may experience from this study will be a decrease in pain during your epidural steroid injection procedure. However, there is no guarantee that you will benefit from being in this research.

Possible Benefits to Others
The results of this research may guide the treatment of patients while undergoing epidural steroid injections in the future.

Section 6. STATEMENT OF CONFIDENTIALITY

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 the Web site at any time. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

6.1 Privacy and Confidentiality Measures

For research records sent to the sponsor, you will be identified by a code number assigned to you for study purposes. The list that matches your name with the code number will be kept in a locked file in your principal investigator's office at your institution.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

6.2 The Use of Private Health Information

Health information about you will be collected if you choose to be part of this research study. Health information is protected by law, as explained in your health care institution's Privacy Notice. If you have not received this notice, please request a copy from the investigator. Your information will only be used or shared as explained and authorized in this consent form or when required by law. It is possible that some of the other people or groups who receive your health information may not be required by Federal privacy laws to protect your information and may share it without your permission.

To participate in this research you must allow the study team to use your health information. If you do not want us to use your protected health information, you may not participate in this study. People usually have a right to access their medical records. However, while the research is in progress, you may not be allowed to see or copy certain information that is related to this research study. This is only for the period of the research. You will be allowed to see that information when the entire research project is complete.

Your permission for the use, retention, and sharing of your identifiable health information will expire 3 years after the completion of the research study. At that time the research information not already in your medical record will be destroyed. Any research information in your medical record will be kept indefinitely.

If you choose to participate, you are free to withdraw your permission for the use and sharing of your health information at any time. You must do this in writing. Write to your study doctor and let him or her know that you are withdrawing from the research study.

If you withdraw your permission:

- We will no longer use or share medical information about you for this research study, except when the law allows us to do so
- We are unable to take back anything we have already done or any information we have already shared with your permission
- We may continue using and sharing the information obtained prior to your withdrawal if it is necessary for the soundness of the overall research
- We will keep our records of the care that we provided to you as long as the law requires.

The research team may use the following sources of health information:

- Information from your medical chart.
- Information provided to the study team during the study.

Representatives of the following people or groups within your may use your health information and share it with other specific groups in connection with this research study.

- The principal investigator at your treatment facility

- The Institutional Review Board
- The Human Subjects Protection Office at your treatment facility
- Members of the research study team
- The sponsor of the study, the Geneva Foundation

The above people or groups may share your health information with the following people or groups outside of your treatment facility for their use in connection with this research study. These groups, while monitoring the research study, may also review and/or copy your original records.

- The Office of Human Research Protections in the U. S. Department of Health and Human Services
- The Uniformed Services University of Health Sciences

Section 7. COSTS FOR PARTICIPATION

There is no cost to participate in this study.

Section 8. COMPENSATION FOR PARTICIPATION

You will not receive compensation to participate in this study.

Section 9. RESEARCH FUNDING

The funding for this study is provided by the Department of Defense (DoD) Defense Health Agency (DHA) through the Uniformed Services University (USU).

Section 10. WHAT HAPPENS TO THE DATA COLLECTED IN THIS STUDY?

The sites involved in this research study work to advance science and public health. The data we collect about you are important to this effort.

If you join this study, you should understand that you will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

How will your data be shared now and in the future?
Sharing data is part of research and may increase what we can learn from each study.
Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas.

Your data may be shared:

- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners
- through government or other databases/repositories

Data sharing could change over time, and may continue after the study ends.

We will do our best to protect and maintain your data in a safe way. Generally, if we share your data without identifiers (such as your name, address, date of birth) no further review and approval by an Institutional Review Board (IRB), a group of people that reviews human research studies, is needed. If data are shared with identifiers, further IRB review and approval may be needed. The IRB will determine whether additional consent is required.

Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation (PM&R) at the Uniformed Services University (USU) is serving as the data coordinating center for this study. As such, staff from MIRROR/USU will have access to your de-identified (meaning that all of your personal identifiers have been removed) research data. This de-identified research data will be kept indefinitely.

The use of your data is required for participation in this research study. If you are not comfortable with the use of your data in future research without further consent, you should not participate in this study.

Section 11. VOLUNTARY PARTICIPATION

Taking part in this research study is voluntary. If you choose to take part in this research, your major responsibilities will include coming to clinic appointments, completing questionnaires, receiving your assigned study intervention during your standard of care pain treatment. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled.
Your study doctor may take you out of the research study without your permission. Some possible reasons for this are: a reaction to your assigned treatment or missed clinic visits. Also, the sponsor may end the research study early. If your participation in the research ends early, you may be asked to visit the investigator for a final visit.

If you will be participating in another clinical trial while in this research, you should discuss the procedures and/or treatments with study doctor. This precaution is intended to protect you from possible side effects from interactions of research treatments or testing.

During the course of the research you will be provided with any significant new findings that may affect your willingness to continue participating in this research.

Section 12. WHAT OTHER THINGS SHOULD YOU KNOW ABOUT THIS RESEARCH STUDY?

What is the Institutional Review Board (IRB) and how does it protect you?

This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study.

For this multi-site study, Johns Hopkins has agreed to serve as the single IRB (sIRB) providing oversight for all sites. You may contact the Johns Hopkins IRB at 410-502-2092 or jhmeirb@jhmi.edu with your questions or concerns.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?

Call the principal investigator for your study site, which is listed in the **"Site-specific Consent Information"** (Part 2 of this consent).

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department.

If you wish to contact the overall study principal investigator(s), use the contact information provided on page one of this consent form.

SITE SPECIFIC CONSENT INFORMATION

Site Name: The Johns Hopkins University
Study Title: Can Distraction Substitute for Procedural Sedation and Improve Tolerance in Patients Receiving Epidural Steroid Injection for Pain? A Randomized Controlled Trial.
JHM IRB Application Number: IRB00255275
Site Principal Investigator: Steven Cohen, MD
Site Principal Investigator Contact Information: Steven Cohen, MD
550 N. Broadway, Suite
Baltimore, MD 21287
Phone: 410-955-1818

Emergency Contact: Steven Cohen, MD
Pager: 410-283-2037

Other Study Contact(s): Mirinda Anderson White, RN
410-955-6488

Introduction:

This study is being done at multiple sites. This part of the consent form includes information about your site and is specific to participation at your site only. Before making your decision, both the site-specific information and general study information will be reviewed with you. You will have the opportunity to discuss any questions, including questions about this portion of the consent document, with your site's study team.

Site-Specific Procedures

In addition to the procedures listed previously in this consent, we would like to ask if you would wear a sticker that will be placed on your forehead while you are getting your procedure. This sticker is a sensor that will be connected to the monitor in the procedure room and will allow us to view and record an electroencephalogram (EEG) during your procedure. EEG shows the electrical activity of the brain. We are hoping that the EEG will show us how the brain reacts to distraction and sedation during your procedure.

YES ☐ I **agree** to allow the Principal Investigator and Johns Hopkins study team members to make and use an EEG recording during my procedure.

NO ☐ I **do not agree** to allow the Principal Investigator and Johns Hopkins study team members to make and use an EEG recording during my procedure.

Compensation for Research-Related Injury:

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

If you are injured you may, for the duration of the study, be eligible for health care services for research-related injuries at a military treatment facility, and this eligibility for health care services extends beyond your participation in the study to such time after the study has ended.

Site IRB Contact Information:

This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

For this multi-site study, Johns Hopkins has agreed to serve as the single IRB (sIRB) providing oversight for all sites. You may contact the Johns Hopkins IRB at 410-502-2092 or jhmeirb@jhmi.edu with your questions or concerns

Additional information about your local site:

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department. You should also call Steven Cohen, MD at 410-955-1818 during regular office hours and at 410-283-2037 after hours and on weekends. **After the tone, enter the phone number where you can be called, press the # key, and hang up.**

If this doctor is not available, the operator will page the "on call physician."

How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

The Department of Defense (DoD) will have access to records for audit purposes.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

Signature Lines:

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT PROCESS

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time

Signature of Participant	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).