UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES
(v. 11.2012)

Project Title: A randomized double blind cross-over trial of continuous intrathecal infusion for assessing patients with chronic noncancer pain who would benefit from treatment with intrathecal drug delivery system (IDDS) implant

Principal Investigator: Salim Hayek, MD, Ph.D.

Introduction/Purpose
You are being invited to take part in a research study because you are going to be scheduled for a test of a continuous "intrathecal infusion" for relief of your back pain. By "intrathecal infusion" we mean putting medicine (or other treatments) directly into the spinal fluid that is around your spinal cord and nerves.

The usual procedure is to see if giving medicine through a catheter directly into the intrathecal space in your spine where there are nerves is helpful in relieving your pain. If the test shows that this is effective, your doctor may recommend that you have a permanent catheter and pump implanted to give you the medicine continuously.

Although this kind of test is commonly done, there are a number of different ways it can be done, with different medicines and for different lengths of time. The purpose of our research study is to learn more about how accurate the test is in predicting who will benefit from an implanted pump when the test is done using an active medication combination compared to an inactive substance (saline solution without medicine). The "extra" or research part of the procedure is testing how much pain relief you get when the active medicines (the usual approach) are given, compared to your reaction to the inactive saline. All patients will receive both solutions at different times. The detailed procedures are described below.

This study is being conducted at University Hospitals Cleveland Medical Center. We hope that 36 patients will take part in the study.

Study Procedures
If your doctor believes you are eligible to be in this study and you decide to participate, you will be asked to read and sign this consent form. You may take this consent form home with you prior to making your decision. You will then be scheduled for the following.

All patients who take part in this study will be admitted to the hospital and stay for 3 days (two nights). As is usually done for any patient being tested for use of an implanted device for pain, you will have already received instruction by video and discussion with your physician about the procedure and the implanted pump.

All patients will go to the Operating Room to have a temporary catheter inserted in to their back, using x-rays to place the catheter in the exact spot needed. Once you are back in your hospital room, a solution (either the active medicines, Fentanyl and bupivacaine, or the inactive solution, the saline) will be given through the catheter, into the space on your spine where there are nerves. The next morning (Day 2) the solution will be stopped for 6 hours. After this, the other solution will be started. That is, if you received fentanyl and bupivacaine during the first infusion, you will then be given the saline solution. If you received saline in the first solution, you will then be given the fentanyl/bupivacaine solution.

Neither you nor your doctors will know which solution is being given first and which is being given second. The order in which the solutions are given will be determined by a process similar to a flip of a coin - -this is called 'randomization.' All patients will receive both solutions, just in a different order. The section below explains more about what happens on each day.

Hospital Day 1
After you have been admitted to the hospital, before you go to the operating room to have the catheter placed, you will be asked to complete some research questionnaires about your pain. The questionnaires will take approximately 10-15 minutes to complete. Once all the questionnaires and other pre-procedure activities are completed, you will have your temporary catheter implant procedure.

Once the temporary catheter implant procedure is finished, you will be taken to the Recovery Room. That is where the first infusion (fentanyl with bupivacaine, or normal saline) will be started. Once you are assigned a bed, you will be transferred to a regular hospital room. The medication infusion will be adjusted periodically by a pain management physician based on how you are feeling and how your pain is.

Throughout the post procedure period, you are encouraged to get up in a chair as well as walk around the hospital ward. This will help the doctors assess how well each infusion helps your back pain.

Hospital Day 2
Infusion #1 will be stopped around 6-7am. One of the pain management doctors will assess you and your pain and make sure your intrathecal catheter is working properly. You will be asked to complete some questionnaires about your pain and the treatment. The questionnaires will take approximately 10-15 minutes to complete.

After Infusion #1 finishes, you will have a four to six hour washout period. The washout period gives your body the chance to get rid of the effects of the first infusion. During the washout period, normal saline will infuse through your temporary catheter to make sure your temporary catheter continues to function. You are encouraged to get up in a chair and walk around during the wash out period. You will answer more questionnaires at the end of the wash out period which will only take a couple minutes.

Around noon, at the end of the washout period, you will be started on Infusion #2 (whichever solution you did not receive the first time). A similar pattern to day 1 will take place.

Throughout the post procedure period, you are encouraged to get up in a chair as well as walk around the hospital ward. This will help the doctors assess how well each infusion helps your back pain.

Hospital Day 3/Discharge
Infusion #2 will finish around 6am. One of the pain management doctors will assess you and your pain, and will remove the temporary catheter. You will be asked to complete some questionnaires about your pain and the treatment. The questionnaires will take approximately 10-15 minutes to complete. Once all this is done, if you are having no problems, you may be discharged from the hospital.

Follow-up
If you did not receive at least 50% pain relief with either of the solutions, you will not be offered a permanent intrathecal pump. We would still like to contact you at 6 and again at 12 months to ask you how your pain is. We will do this by calling you on the telephone.

If you did have at least 50% pain relief with one or both solutions, you will be offered a permanent implanted intrathecal pump. Regardless of which solution you responded to, the permanent pump would be filled with active medicine. The decision to proceed with having the pump inserted is up to you. Regardless of whether you decide to have the permanent pump implanted, we would like to ask to complete pain related questionnaires around 6 and 12 months. This can be done over the phone, or if you do decide to have the pump implanted, we can ask you the questions when you come back for a scheduled pump refill visit. The questionnaires will take approximately 10-15 minutes to complete.

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Risks

Doing a test of your response to intrathecal medicine is the usual procedure for evaluating whether you might benefit from a permanent implanted pump. Therefore, risks of having a catheter inserted in your back and receiving pain medication through the catheter are all risks that you would experience even if you do not take part in the research.

Comparing these specific active medicines (fentanyl and bupivacaine) to the inactive solution (saline) is part of the research. There is an added risk of you experiencing increased back pain with the normal saline solution because it does not contain the pain medication. You also will be in the hospital an extra day in order to complete the full test.

It is unlikely, but possible that some patients may respond to the saline infusion during the test, but then would receive the active medicine in their permanent pump. This may also be associated with less pain relief or no pain relief over time.

Questionnaires/Research: The questionnaires will be used to compare the outcomes of each infusion treatment. The only risks of the questionnaires include potential breach of confidentiality of your medical record information and associated privacy. This risk will be minimized by assigning you a unique study number and only attaching your questionnaire answers to the study number, not your name. This number will be kept in a locked area with only the study team having access.

Benefits

You may or may not benefit from participating in this study. By comparing active medicine with saline during the test, we hope we will have an accurate way to predict if a permanent pump will help your pain, but this cannot be guaranteed. We hope that the information we gain from the study will be useful in the care of those who suffer from the disease.

Alternatives to Study Participation

If you choose not to take part in the study, you will continue with your current treatment for your back pain. This includes having the test of the intrathecal done using the usual protocol, which only includes testing the active medicine.

You may choose to withdraw from the study at any time.

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Consequences of Withdrawing or being discontinued from the Research

There is no penalty to you if you would like to withdraw your participation from this study. Normal standard of care procedures will be discussed and offered by your doctor.

You may be discontinued from the research study if you do not follow your doctor's advice or if we are unable to reach you for follow up visits. It is also possible that your study doctor may stop your participation in the research study if he/she feels it is in the best interest of your health.

Financial Information

All procedures involved in the study for diagnosis and treatment are considered "standard of care". Standard of care are procedures that you would normally undergo whether you choose to participate in the study or not. For study purposes, standard of care applies to the costs of the procedure, medications and hospitalization, and you/your insurance will be billed.

You will receive no monetary compensation for taking part in the study.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Confidentiality

Results of this research study will be treated as confidential information and the results will not be included in your medical record. Similarly, your medical history will also be treated as confidential with no identifiable information released or shared with anyone outside the study team. If the study results are published, your name will not be used. Once all your results are collected, any identifiers will be removed and the information assigned a code. The data will be identified by a study number and not by your name or identifying information. The code assignment key will be maintained by the Principal Investigator, Salim Hayek, MD and his research staff on a password protected computer kept in a locked area. Access to the code key will be limited to the Principal Investigator and study personnel.

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Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. If your records are reviewed your identity could become known.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled "A randomized double blind cross-over trial of continuous intrathecal infusion for assessing patients with chronic noncancer pain who would benefit from treatment with intrathecal drug delivery system (IDDS) implant" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Salim Hayek, MD, and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Cleveland Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you:

- Name, initials, address, telephone number, age and other demographic information
- Your medical history, past medical records (including history and diagnosis of your disease and your family medical history.
- Medical data, including your research evaluation findings.
- Records about your study visits and information obtained during this research.

This PHI will be used to assess whether receiving bupivacaine via your pain pump in small doses with your opioid pain medicine significantly improves your back pain and ability to function. Your access to your PHI may be limited during the study to protect the study results.

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Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research:

- Staff from the principal investigator's medical practice at UHCMC
- Staff at University Hospitals Cleveland Medical Center, including the Center for Clinical Research and the Law Department, Institutional Review Board, Federal agencies or any agency when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to:

Salim Hayek, MD, Ph.D
University Hospitals Cleveland Medical Center
Department of Anesthesiology/Division of Pain Management
11100 Euclid Ave., Mather Pavilion B270
Cleveland, OH 44106

If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

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Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Contact information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator, Salim Hayek, MD, can also be contacted at 216-844-3771. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

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X	
Signature of Participant	Date
X	
Printed Name of Participant	

X	
Signature of Witness (if applicable)	Date
X	
Printed Name of Witness	

X	
Signature of person obtaining informed consent	Date
X	
Printed name of person obtaining informed consent	