STUDY: Cooled Radiofrequency Denervation for Chronic Pain
PROTOCOL NO: 105-17-0004
STERLING IRB ID 6205-001
DATE OF IRB REVIEW 01/30/18 DATE REVISED: 07/12/18

PARTICIPANT INFORMED CONSENT FORM AND
AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

STUDY TITLE:	A Prospective, Single-center, Pilot study Of in vivo lesion characteristics post Cooled Radiofrequency Denervation as Treatment for Chronic Pain.
PROTOCOL NO:	105-17-0004
STUDY DOCTOR:	Mehul J Desai, MD
STUDY SITE:	International Spine, Pain & Performance Center 2141 K St. N.W., Suite 600 Washington, DC 20037
TELEPHONE:	202-808-8295 (24 hours)
SPONSOR:	International Spine, Pain and Performance Center

INTRODUCTION

You are being asked to take part in a research study. Participation in this research study is completely voluntary. This means that it is your choice whether, or not, you want to participate in the study. Before agreeing to participate, it is important that you read and understand the following information. This consent form explains why the study is being conducted and describes what will happen during the study if you choose to participate. It tells you about the benefits, risks, discomforts, and safety measures of the study. It also tells you about other options that are available to you if you decide not to participate.

This consent form may contain words that you do not understand. If you have questions, please ask the study doctor or a member of the study staff to answer them. Please read the information carefully and discuss it with anyone you want. This may include a friend or a relative, or another healthcare provider. You can take as much time as you want, and you may take home an unsigned copy of this consent form to think about the study before making your decision.

Once you know about the study and the tests that will be performed, and if you decide you want to participate, you will be asked to sign this consent form. You will be given a copy of the signed consent form for your records. You are under no obligation to join the study, and if you decide not to join, it will not affect your medical care. You are free to leave the study at any time, and your study doctor's attitude toward you will not change whether, or not, you choose to participate.

PURPOSE AND DESCRIPTION OF THE RESEARCH STUDY

You are being asked to participate in this research study because you have had joint pain in a specific part of your body for a long time (neck, upper back, lower back, buttocks, hip, knee).

Joint pain may be associated with inflammation (swelling) and degeneration (breakdown) of the joint which worsens over time. It affects the entire joint, including bone, cartilage, ligament, and muscle. When this happens, you may experience pain and a loss of function.

There are several treatments that can sometimes help this problem, including drugs, braces/wearable devices, several types of injections, procedures and even surgery. Your study doctor has determined that your pain may benefit from treatment of radiofrequency denervation (lesioning) to the nerves serving the joint or area where you have pain. This procedure involves testing which nerves are causing pain, then treating them to Stop sending pain messages.

The purpose of this research study is to collect detailed pictures of the effects of radiofrequency lesioning. This study involves using MRI imaging to evaluate the effects of Cooled Radiofrequency Ablation (CRFA). Radiofrequency ablation involves the use of an electrical current produced by a radio wave to heat up a small area of nerve tissue, resulting in decreased pain signals to the area. Specifically, we would like to understand the size and characteristics of lesions created by ablation.

This study will be done at the International Spine, Pain & Performance Center only and will include about 15 men and women age 21 and older.

STUDY DESIGN

The study will occur in three (3) parts: Screening and pre-MRI, if applicable, the radiofrequency lesioning treatment, and a follow-up MRI within 2-7 days after the treatment. Whether you will need an MRI before the treatment depends on the type of treatment you will be having. Your study doctor and their staff will help you manage your visit schedule during the study.

The diagram below and the description that follows may help you understand the study plan.

Study Design

Pre-Treatment Screening Phase

During the Screening Phase, the study doctor will review your medical records and perform tests to determine if you are eligible to participate. If you are having the procedure in your sacroiliac joint or if your study doctor determines it is necessary, you will have an MRI before the treatment, within 30 days of the treatment.

CRFA Treatment Visit

You will have the cooled radiofrequency lesioning treatment the same as you would have if you were not participating in the study.

Post Treatment Follow-up Phase

You will have an MRI 2-7 days after CRFA treatment and have the normal follow-up visits you would have if you were not participating in the study.

PROCEDURES

Your study doctor will perform some medical tests at your visits. Different tests will be performed at different visits. Many of the procedures that are required for the study would be done even if you were not in the study. Below is a description Of which tests and procedures will be done.

SCREENING VISIT (VISIT 1)

In most cases, Screening should be completed in one visit. It may take several visits depending upon what procedures you have already completed as part of your normal treatment for your pain. Many of the procedures may have already been done for you as you have been in pain for a long time. Your study doctor will try to use the results from previous procedures to determine if you are eligible for the study. If you have had CRFA previously, you will be unable to participate in the study.

Once you have signed this consent form indicating you want to be a part of the study, you will be screened for the study. The items that need to be completed prior to or during the screening are:

- Medical History: Your study doctor will ask you some medical questions about your health and your medical history.

- Physical Exam: You will have a physical exam. The physical exam will not include a pelvic, rectal or breast exam. Your vital signs will be taken. Vital signs include blood pressure, pulse, temperature, rate of breathing, height, and weight measurements. Your study doctor will exam the area where you have pain.

- Medication History: You will also be asked questions about your medication history.

- Urine Pregnancy Test: If you are a woman who could possibly become pregnant, you will have a pregnancy test if it has been more than 30 days since you have had one performed by this doctor. If your pregnancy test is positive, you will not be able to continue in the study.

- Pre-treatment MRI: If necessary, you will have an MRI before the treatment (within 30 days)

TREATMENT VISIT (VISIT 2)

Everyone who enrolls in the study will receive treatment at Visit 2. You will receive the CRFA treatment the same as you would have if you did not participate in the study.

- Your study doctor will ask you questions about your health and medications since your last visit and document any problems that you might have.
- If there is a possibility you could become pregnant, and it has been 30 days since your last pregnancy test for the study, your doctor may ask you to perform a urine pregnancy exam prior to receiving the procedure.

Your Treatment Visit will take about I lh- 2 hours, and this is when you will receive the CRFA treatment. The actual procedure will take between 30 and 45 minutes during this visit. It is possible that you could receive this procedure on the same day you are entered into the study.

After completing the above tests, you will receive the CRFA treatment at this visit

MRI VISIT (VISIT 3 - 2-7 days after the procedure)

Everyone enrolled in the study will have an MRI of the area the procedure was done 2-7 days after the procedure.

UNSCHEDULED VISIT

If you have had any unexpected problems or issues or in the event you need to see your study doctor, you can have a visit called an "unscheduled visit." This is optional and will happen only if you need it.

RISKS

There are potential risks related to having an MRI. Your study doctor will explain all of these to you.

Risks Related To MRI

MRI is a type of medical imaging that takes detailed pictures. It is a common tool used by doctors to evaluate patients and uncover the cause of their pain. The risks associated with an MRI relate to the powerful magnet. If you have metal in your body, this could pose a safety hazard. Tell your doctor if you have metallic joint prostheses, artificial heart valves, an implantable heart defibrillator, a pacemaker, metal clips, cochlear implants or a bullet, shrapnel or any other type of metal fragment.

If you had or currently have any type of renal or kidney impairment, tell your study doctor prior to signing this form. Certain contrast agents are used in conjunction with the MRI procedure. These contrast agents are used to help define the area of interest and allow the doctors to better interpret your MRIs. If you have renal or kidney impairment and fail to mention this to your study doctor, you may suffer serious pain and other health related complications from the MRI procedure. It is highly recommended that you inform your study doctor of any previous or on going renal/kidney issues.

Some people may experience claustrophobia (fear of enclosed space) during an MRI.

PREGNANCY RISKS

The risks to the human embryo, fetus, or breast-fed infant are unknown.

You cannot take part in this study if you are pregnant. Signing this consent form means that you are willing to have a urine pregnancy test during Screening.

POSSIBLE BENEFITS

You will not directly benefit from your participation in this study. Your taking part in this study may help patients in the future. Specifically, we may be able to optimize the procedure to ensure that it is as effective as possible.

COSTS

The study doctor receives compensation from the study sponsor for activities unrelated to this study. If you have any concerns about this financial relationship, please ask the research staff.

There will be no additional charge to you for being in this study.

PAYMENT FOR PARTICIPATION

There will be no payment for participation in this study.

COMPENSATION FOR INJURY

If you suffer side effects, injuries, or illness related to the study, contact your study doctor. Your study doctor will provide medical care and advice during and after the study. Treatment for injuries may include, if necessary, laboratory tests, x-rays, and/or other procedures used in diagnosis and treatment. These treatments will be offered under your normal insurance care.

LEGAL RIGHTS

The above section does not restrict your right to seek legal assistance. You do not waive any legal rights by signing this consent form.

RESEARCH RESPONSIBILITIES

Study participants are responsible for complying with all study requirements when they make an informed choice to enroll in a study. If you agree to participate in this study, you should make every effort to comply with your study doctor's instructions, follow protocol procedures, and provide honest and accurate information during the course of the study. Following the requirements of the protocol can prevent unexpected harm to you, and will maintain the scientific integrity of the study.

ALTERNATIVE TREATMENT

You do not have to take part in this study to receive treatment for your condition. You can get the CRFA treatment without signing up for this study. There are several other alternative treatments available as well. One choice is not to be in this study and to continue treatment with your doctor. Please talk to your study doctor about alternative treatment options.

SOURCE OF FUNDING

The study is being funded by a healthcare company, Halyard Health, Inc.

CONFIDENTIALITY

MRI images and information regarding lesion characteristics from this study will be provided to Halyard Health or any persons or companies which are contracted to have access to the research information during and after the study.

The MRI images will also be provided to a neuroradiologist, Dr. Yair Safriel. He will evaluate the images and characterize the lesions.

The information may also be given to the U.S. Food and Drug Administration (FDA). It may be given to governmental agencies in other countries where the product may be considered for approval. Medical records, which identify you and the consent form signed by you, may be looked at and/or copied for research or regulatory purposes by Halyard Health or companies/people hired to run the study, and by the following agencies or organizations:

- the FDA
- Department of Health and Human Services (DHHS) agencies
- governmental agencies in other countries
- Sterling Institutional Review Board (IRB)
- People hired to help manage the study.

Your identity will not be disclosed to these companies. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

The study doctor will assign a code number to you that will be used to collect and manage your information in the study. Your initials may also be used. Halyard Health and its representatives may review or copy your personal health information at the study site. Regulatory authorities and Sterling IRB may also review or copy your information to make sure that the study is done properly or for other purposes required by law. When information is copied, your personal identifying information (name, etc.) should be replaced with the study number before the information leaves the doctor's office.

The data from this study may be published, if so no identifying information will be included.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. However, all recipients of any information pertaining to your participation in this research study will treat the information as confidentially as possible based on applicable privacy laws and regulations and will not be made publicly available.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this study is 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.

The study doctor, a representative of the study doctor, or the FDA (Food and Drug Administration) may take you out of the study without your consent at any time for the following reasons:

- You do not meet the study conditions;
- You don't follow the directions of the study;
- It appears to be medically harmful;
- You do not consent to continue in the study after being told of changes in the research that may affect you,
- Pregnancy,
- The study is stopped;
- Administrative reasons
- Or for any other reason.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

The United States government has issued a new privacy rule to protect the privacy rights of subjects. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. The consent form you are reading, called an "Authorization," describes your rights and explains how your health information will be used and disclosed (shared).

In working with Halyard Health, the study doctor will use and share personal health information about you. This is information about your health that may also include your name, address, telephone number, or other facts that could identify the health information as yours. This includes information in your medical record and information created or collected during the study. This information may include your medical history, physical exam, and laboratory test results. Some of these tests may have been done as part of your regular care. The study doctor will use this information about you to complete this research.

By signing this consent form, you allow the study doctor to use your personal health information to carry out and evaluate this study. You also allow the study doctor to share your personal health information with:

- Halyard Health and its representatives
- The radiologist who will be characterizing the lesion, Dr. Yair Safriel
- Sterling IRB
- the U.S. Food and Drug Administration (FDA)
- other regulatory agencies

Your personal health information may be further shared by the groups above. Once your information has been given to others, there is a risk that your information will be given to others without your permission.

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this consent form you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.

You may choose to withdraw this authorization at any time, but you must notify the study doctor in writing. Send your written withdrawal notice to:

International Spine, Pain & Performance Center
2141 K Street, NW
Suite 600
Washington, DC 20037

If you withdraw from the study and withdraw your authorization, no new information will be collected for study purposes unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be utilized.

If you withdraw from the study but do not withdraw your authorization, new personal health information may be collected until this study ends.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

Your study doctor will keep this authorization for at least 6 years.

If you do not sign this Authorization, you cannot participate in this research study or receive study related treatment. If you withdraw this authorization in the future, you will no longer be able to participate in this study. Your decision to withdraw your authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

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

STUDY CONTACT FOR QUESTIONS/IRB CONTACT

If you have any questions about your participation in this research study, if you have questions, concerns, or complaints about the research, or if you feel that you have experienced a research related injury or a reaction to the study device, please contact:

Study doctor name: Dr. Desai or Dr. Sayal
Telephone number(s): 202-808-8295 (24 hours)

A medical professional will be provided to assess you if needed.

If you have questions about your rights as a research participant or if you have questions, concerns, input, or complaints about the research, you may contact.

Sterling IRB
6300 Powers Ferry Road, Suite 600-351
Atlanta Georgia 30339
Telephone: 1-888-636-1062 or 770-690-9491
E-mail: Info@sterlingirb.com

Sterling IRB is a group of people who perform independent review of research.

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

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.

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PARTICIPANT'S STATEMENT OF CONSENT

I choose to participate in this study. I have read all of the above and I have been given the information about the use and disclosure of my health information for 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.

I have been given the opportunity to ask questions about this study and my questions have been answered to my satisfaction. By signing this consent form, I have not given up any of my legal rights.

I will receive a signed copy of this form, which has 10 pages.

_____
Printed name of Participant

_____ _____ _____
Signature of Participant Date Time

_____
I am witness to the signature above and have fully explained the study as stated.

_____
Authorized Study Staff - Person Conducting Informed Consent Discussion

_____ _____ _____
Signature Title Date

_____ _____
Signature of Investigator Date
(if different from above)