TITLE: The Effect of Auriculotherapy Combined with an Interscalene Block for Post-Operative Pain Management Following Rotator Cuff Surgery A Randomized, Placebo-Controlled Trial

NCT03860259

Date: August 4, 2020

University of Pittsburgh

Department of Anesthesiology

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: The Effect of Auriculotherapy Combined with an Interscalene Block for Post-Operative Pain Management Following Rotator Cuff Surgery A Randomized, Placebo-Controlled Trial

PRINCIPAL INVESTIGATOR: Jacques Chelly, MD, PhD, MBA
Professor of Anesthesiology
UPMC Shadyside
5230 Centre Avenue
Pittsburgh, Pennsylvania 15232
412.623.6904

Source of Support: Department of Anesthesiology

Why is this research being done?
The opioid epidemic has warranted research into alternative methods of pain relief. What's more, the adverse side effects of opioids such as post-operative nausea and vomiting, respiratory complications, weakening of the immune system, and constipation are less than ideal. Therefore, non-pharmacologic pain therapies pose a great benefit to surgical patients who may otherwise become susceptible to opioid addiction as well as the harmful side effects that result from taking these medications alone. For example, the interscalene block (a continuous pain medication infused into the shoulder) is the gold standard for post-operative pain management following rotator cuff surgery; even though it is not itself an opioid, the duration of the block does not cover rehabilitation, and therefore, patients are discharged from the hospital with an opioid prescription. This practice merits the investigation of a non-pharmacologic alternative to post-discharge pain therapy. One such therapy being investigated is auriculotherapy whereby an acupuncture technique is used to relieve pain. We are hoping that by incorporating this device into post-surgical pain management, patients will require less opioids, which will in turn reduce harmful side effects and the risk of addiction. This research device is not approved by the United States Food and Drug Administration (FDA).

Who is being asked to take part in this research study?
You are being invited to participate in this research study because you have agreed to undergo shoulder surgery.

People being invited to participate must be over 18 years of age.
Fifty (50) subjects are planned to be enrolled in this research study.

What procedures will be performed for research purposes?

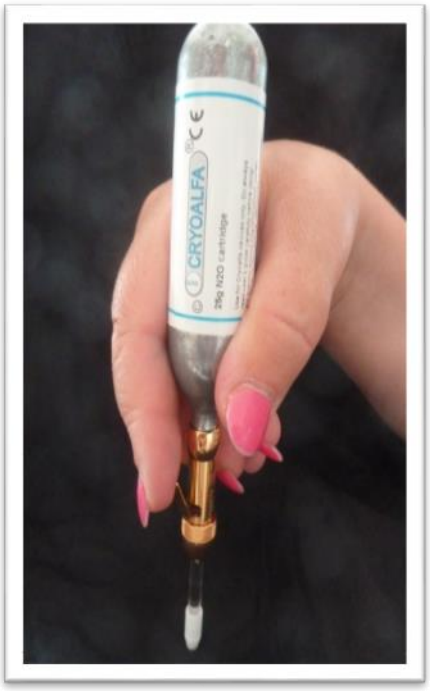
Screening Procedures:
There are no specific screening tests or procedures for this research study. Your medical records will be examined

by your anesthesiologist to determine your eligibility for the study.

Procedures:

If you qualify to take part in this research study, you will undergo the procedures listed below:

After you sign an informed consent form, you will be enrolled into the study. A cryopuncture device will be applied to the ear by Dr. Jacques Chelly or a trained research designee after surgery in the recovery room (PACU). Participants will be randomly assigned to one of two groups: the intervention group, where nitrogen gas is used to perform the cryopuncture auriculotherapy, or the control group, where no gas will be used, acting as a placebo. A picture of the cryopuncture device is found below:



Regardless of which group you are randomized to, the cryopuncture device will be held to the same nine points on your ipsilateral ear (the ear which is on the same side upon which you will have shoulder surgery). Even if gas is not used (control group), you still may hear and feel a sensation that is indistinguishable from the real nitrogen gas treatment. However, treatment with nitrogen gas instantaneously freezes the tissue on the ear, which may cause a mild stinging sensation for a few seconds during and after treatment.

You will also receive the interscalene block as it is the standard pain control method. Other forms of analgesia (pain medication) will be permitted during study participation. If you no longer wish to participate in the study for any reason, you may withdraw at any time.

Monitoring/Follow-up Procedures

Hospital Discharge: At the time of hospital discharge, you will be given a subject diary to record pain medication and pain scores while at home. You will also be asked to report a patient pain satisfaction score (0-6), as well as a pain at rest and pain with movement score (0-10) prior to being discharged.

Subject Diary: You will be asked to take home and complete a diary after discharge. You should complete this diary

right before bedtime at the end of each post-operative day. You will record total narcotic/pain medication consumption, pain score and patient pain satisfaction score every day for the first 5 days post-operative, two-weeks after surgery, and then once a month for 3 months (post-operative days 14, 30, 60 and 90). You will be called by research staff on Day 3 post-operatively, and then on post-operative Day 14, Day 30, Day 60 and Day 90 as a reminder to complete diary entries, assess any adverse events recorded in the diary (such as pain at treatment site, constipation, and/or nausea and vomiting), and administer the *Functional Recovery Survey (SF-12)*. You will be called for a final time on post-operative Day 90 to receive instructions on returning diary and report an overall patient satisfaction score.

Pain Medication Consumption: Rescue analgesia (pain medication) may be offered. Pain medication consumption will be measured every 24 hours for five days post-operatively (post-operative days 1, 2, 3, 4 and 5), two-weeks after surgery, and then once a month for 3 months (post-operative days 14, 30, 60 and 90).

NRS Pain Scale: Pain level after surgery will be measured once every 24 hours for five days post-operatively (post-operative days 1, 2, 3, 4 and 5), , two-weeks after surgery, and then once a month for 3 months (post-operative days 14, 30, 60 and 90). This will be measured using a Numeric Rating Scale (NRS), where 0 equals no pain, and 10 is the most severe pain imaginable. This pain score will be recorded in your diary.

Patient Pain Satisfaction Score: This will be measured using a numeric rating scale where 0 indicates the worst satisfaction while 6 indicates the best satisfaction. This will be measured as a part of your diary on post-operative days 1-5 and post-op day 14, 30, 60 and 90.

Adverse Events: There is a section in your diary about reporting adverse events. This is where you should record any incidents with your health that concern you, such as itching, constipation or nausea and vomiting.

Functional Recovery Survey (SF-12): On the day of your surgery as well as two-weeks and 1, 2 and 3 months post-surgery (post-operative days 14, 30, 60 and 90), you will be asked to complete a survey indicating your overall satisfaction as well as satisfaction as it pertains to pain management.

Overall Patient Satisfaction Score: You will be asked to assess your overall patient satisfaction at the final post-op day 90 phone call, with 0 being least satisfied and 10 being most satisfied.

What are the possible risks, side effects, and discomforts of this research study?
There are risks associated with your surgery, anesthesia, and hospitalization. These risks will be discussed with you by your surgeon and anesthesiologist and are independent of your participation in this research study.

Auriculotherapy: This procedure may be associated with the risk of local skin reaction and infection at the point of application. The investigator applying the device will have had the appropriate training to avoid the risk of skin blistering. Auriculotherapy site will be monitored for any signs of infection or delayed healing. Subjects will be screened for eligibility to exclude individuals with vascular issues that could delay healing, such as Raynaud's Disease.

Nitrogen Gas: If randomized to the intervention arm of the study, you will be treated with nitrogen gas. You may feel a sensation of stinging, mild burning, or slight pain during the treatment or immediately afterwards. This can last from 1 to 30 seconds, rarely more.

Your medical record will be accessed by study team. Some of the information reviewed in the medical record include

medical history, surgical and anesthesia record, medication record and pain scores. All of your medical record and study-related information will be considered protected health information and will be kept confidential per HIPAA privacy act. There is, however, a possibility of breach of confidentiality. That is, in very rare cases, people not associated with this research study may inadvertently see your identifiable research results. We will do everything in our power to prevent this from happening by keeping all research records in locked files, and identify all specimens and medical information by a research record number, rather than by your name or social security number. The codebook containing your name and number will be kept secure by the Study Team.

You can speak with your anesthesiologist if you have any questions or concerns regarding the implications and frequencies of each risk.

What are possible benefits from taking part in this study?
You may benefit by requiring fewer post-operative narcotics which may result in fewer opioid-related side effects.

What treatments or procedures are available if I decide not to take part in this research study?
If you decide not to take part in this research study, you will receive the standard anesthesia and post-operative care dictated by the Enhanced Recovery After Surgery (ERAS) protocol, which is the standard of care in this institution.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

You will be promptly notified if, during the conduct of this research study, any new information develops which may cause you to change your mind about continuing to participate.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?
Some of the services you will receive during this study are "research only services" that are being done only because you are in the study. This includes the auriculotherapy treatment. These services will be paid for by the study and will not be billed to your health insurance company or you.

You will be responsible for paying any deductibles, co-payments or co-insurance that are a normal part of your health insurance plan.

Will I be paid if I take part in this research study?
You will not receive any payment for participating in this research study.

Who will pay if I am injured as a result of taking part in this study?
University of Pittsburgh researchers and their associates who provide services at UPMC (UPMC) recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research. If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

Who will know about my participation in this research study?
Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research results. We will attempt to preserve your medical record and participation in this study as confidentially as possible, but breach of confidentiality is a risk of participation.

Will this research study involve the use or disclosure of my identifiable medical information?
This research study will involve the recording of past, current and/or future identifiable (pertaining to only you) medical information from your hospital and/or other health care provider (e.g. physician office) records. This information that will be recorded will be limited to diagnostic information, lab results, medications, and medical history. The information will be used to determine your eligibility for this study and to follow your care once you are enrolled in the study.

This research study will result in identifiable information that will be placed into your medical records held at UPMC and the UPMC Cancer Centers. The nature of the identifiable information resulting from your participation in this research study that will be recorded in your medical record includes response to study treatment including adverse events (side effects).

Who will have access to identifiable information related to my participation in this research study?
In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

Authorized representatives of the University of Pittsburgh Institutional Review Board may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

Authorized representatives of the study team, who are also part of the Department of Anesthesiology and the Acute Interventional Perioperative Pain Service, will review and/or obtain identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data.

Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).
In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate

agencies.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?
The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for an indefinite period of time.

May I have access to my medical information that results from my participation in this research study?
In accordance with the UPMC Notices of Privacy Practices document that you have been provided, you are permitted access to information (including information resulting from your participation in this research study) contained within your medical records filed with your health care provider.

Is my participation in this research study voluntary?
Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Your anesthesiologist is involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your anesthesiologist.

May I withdraw, at a future date, my consent for participation in this research study?
You may withdraw, at any time, your consent for participation in this research study. Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If I agree to take part in this research study, can I be removed from the study without my consent?
It is possible that you may be removed from the research study by the researchers if, for example, you have an unexpected change, complication in your anesthesia or surgery or serious adverse reaction to acetaminophen. If you are withdrawn from participation in this research study, you will still be treated for your post-surgical pain. Please consult your surgeon or anesthesiologist if you have any further concerns.

****

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the principal investigator listed on the first page of this consent document at the telephone number given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this research study and to authorize Dr. Chelly and the members of his research team to access my medical records and extract research data from them, as described in this document. A copy of this consent form will be given to me. Also, I further certify that no research component of this protocol was begun until after the consent form was signed.

_____
Participant's Signature

_____ _____
Printed Name of Participant Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____
Printed Name of Person Obtaining Consent Role in Research Study

_____ _____
Signature of Person Obtaining Consent Date