Title: Postoperative Pain management in Patients Undergoing IMN Fixation After Closed Tibial and Femoral Fractures

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PROTOCOL NUMBER:

SPONSORED BY: The Orthopedic Department of the School of Medicine of the University of Puerto Rico

INVESTIGATORS: Lojo Sojo MD., Hans W. Hess MD., Ruben Tresgallo Pares MD., Marcantonio Pinci MD., Gerardo Olivellas MD., Pedro Rullan MD., Carlos Guevara BS, Juan Gonzalez Ramos BS.

CENTERS: University District Hospital

CONTACT NUMBER: 787-365-5755

This consent may have words that you do not understand. You can ask the investigators to explain the words or information you do not understand. You can also take home an unsigned copy of this consent to study or discuss with your family and friends.

INTRODUCTION:

You have been invited to participate in a research study. Before you decide to participate in the study please read this consent carefully. Ask all the questions you think are necessary to make sure you understand the study procedures, including risks and benefits.

PURPOSE OF THE STUDY:

The purpose of this study is to determine whether oral acetaminophen and IV ibuprofen are viable alternatives to opioid medication regimens for pain management for tibial and femoral shaft fractures treated with intramedullary nailing. With this data we will be able to offer a better service to our future patients, being able to present objective results from past patients. The results will clarify doubts about the benefits of avoiding the use of opioids in people who have been treated surgically with intramedullary nailing for tibial and femoral fractures.

STUDY PARTICIPANTS:

You have been invited to participate in a research study about the use of oral acetaminophen and IV ibuprofen for pain management after being treated with intramedullary nailing for tibial and femoral shaft fractures. You have been invited to participate because you fall into the group of people eligible to participate; you are at least 18 years old and seek care from the orthopedic trauma surgery department at the School of Medicine of the University of Puerto Rico. One hundred and fifty adults older than 18 years of age, who have undergone tibial and femoral intramedullary nailing classified as ASA I/ASA II as per the American Society of Anesthesiologists physical status classification system, will be included regardless of their sex, gender, race, ethnicity, religion, occupation, and social or economic status. Patients with history

of recent use of opioids; hypersensitivity to NSAID and/or acetaminophen; impaired renal, cardiac, or hepatic function; history of gastrointestinal bleeding; history of substance abuse; polytraumatized; pregnant women; mentally incompetent; or inability to consent will be excluded from the study. Minors of less than 18 years of age will be excluded because this musculoskeletal fracture is extremely rare in minors. Patients need to be able to read and write since they are the ones who will complete the consent form.

PROCEDURES:

If you agree to participate in this study, you will be aleatory assigned to either a group receiving opioid medication or another group receiving non-steroidal anti-inflammatory medication combined with acetaminophen for post-operative pain control. We will record variables such as sociodemographic, past medical history, diagnosis /fracture type, highest educational level, allergies, history of illicit drug use, and pain intensity measurements using a Visual Analogue Scale for pain. Post-operatively the first questionnaire will be given 12 hour postoperatively and during subsequent twelve hours intervals until discharge. Each evaluation will last about 15 minutes, for a total maximum of 60 minutes. The information will be kept confidential, saved anonymously and in no case will your personal information be disclosed. You won't be identified by name but rather by a number.

The purpose of it is to compare if there was a change, improvement or worsening, in your pain level as a result of surgery and side effects from pain medications. At the end of the final assessment and after comparing the results, your personal information will be eliminated in order to maintain your anonymity and a bias.

RISKS OR DISCOMFORTS:

Your participation in this study is completely voluntary. You can withdraw from the study at any time. It is considered that participating in this study carries minimal risk. You may feel that pain medications do not adequately manage your pain. If the pain becomes overwhelming you may choose to opt out of the treatment group and have the PI (Dr. Lojo) analyze the your individual case and tailor the pain medication to their needs..

BENEFITS:

You are not expected to receive any direct benefit from this research study, such as a reward. However, your experience will contribute to the society as it will help test out tools that may be used to combat the opioid epidemic. The information collected from this research study could lead to strengthening the knowledge of the orthopedic surgeon and reinforce the multidisciplinary management that acute fracture surgery entails.

COSTS:

This study does not have any additional cost for the participant.

PARTICIPANT INCENTIVE:

There will be no remuneration for participating in the study.

TREATMENT ALTERNATIVES:

There will be 2 alternatives for pain control in this study, yet they will be aleatory assigned. A group that consists of patients who received oral acetaminophen and IV ibuprofen for pain and another group who received morphine and oxycodone in combination with paracetamol for pain. You are free to refuse to participate in this study and will not be penalized for it.

PRIVACY AND CONFIDENTIALITY:

The researchers will take all necessary measures to minimize any privacy breach. All the information we obtain will be kept in a password protected Google Sheet and maintained in confidentiality. This means that it will be treated as personal information that only the Principal investigator (Dr. Lojo Sojo), and the study coordinator (Dr. Olivellas) will have access to your personal information. They will then remove your name from the information collected in a process we refer to as de-identification. Only then, will the de-identified information will be available to the researchers involved in the study, named at the beginning of this document. The results of this study could be published in scientific journals or presented in professional reunions, but your identity will never be published, and all data will be analyzed as a group. Individual results or any personal information about you will not be provided to a third party. This authorization will remain valid until the culmination of the study unless you decide to cancel it before it ends. You can cancel this authorization by sending a written notification to the principal investigator at the following address:

Dr. Lojo Sojo

Orthopaedic Department

UPR-Medical Sciences Campus

PO Box 365067

San Juan, PR 00936-5067

Your authorization for the access and use of your protected personal health information for purposes of this study is completely voluntary. Unfortunately, if you decide not to sign this document you will not be able to participate in this study.

COMPENSATION FOR DAMAGES:

In the event of suffering physical and/or mental damage as a result of the research study, you will receive free medical care at the University District Hospital or in any other hospital designated by the Rector of the Medical Sciences Campus of the University of Puerto Rico. The University of Puerto Rico or the investigators do not intend to provide direct compensation to you. However, by signing this document you do not waive your legal rights.

PARTICIPATION AND VOLUNTARY WITHDRAWAL:

Your participation in this study is voluntary. You can decide not to participate or to withdraw from the study at any given moment. Your decision will not result in any penalty or loss of benefits or services that you have the right to have. If necessary, your participation in this study could be suspended in any given moment by the researcher with your consent.

FUNDS TO PAY FOR THE STUDY:

This study does not receive any kind of funds.

QUESTIONS:

If you have any question about the study, your participation in it, or if you suffer any lesion related to this study, please call:

Dr. Lojo Sojo at 787-764-5095 or
Dr. Hans Hess at 787-365-5755

If you have any question about your rights as a participant, you can contact:

Oficina de Protección de Participantes Humanos en Investigación
Universidad de Puerto Rico
Recinto de Ciencias Médicas
Telephone: 787-758-2525 Extensions: 2510, 2515
E-mail: opphi.rcm@upr.edu

Do not sign this document if you have not had the opportunity to ask questions and have received a satisfactory response to them. If you agree to participate in the study, you will be given a copy of this dated and signed consent and with the IRB's seal of approval for your records.

CONSENT:

I have read the information contained in this consent or the consent has been read to me. All my questions about my participation in this study have been answered. I freely accept to participate in this study. By signing this consent, I have not waived my legal rights.

_____
Name of participant

_____
Signature of participant
Date_____

_____
Name of the researcher that obtains informed consent

_____
Signature of the person that obtains informed consent
Date_____

_____

Authorized Legal Representative Signature Date_____

_____

Authority of Authorized Legal Representative of the Participant / Relationship with the Participant

When this form is read to the study participant

I agree that the information described in this consent form and any other written information that has been given to the participant has been properly explained and has apparently been understood by the participant (or his authorized legal representative). The participant (or the authorized legal representative of the participant) has freely consented to participate in this research project.