Pregabalin vs. Gabapentin on Reducing Opioid Usage in Trauma Patients

NCT# 04705480

IRB Approval Date: 10/16/23

CAMC Health Education and Research Institute, Inc. (CHERI)
Charleston, West Virginia

OUTCOMES RESEARCH
INFORMED CONSENT TO PARTICIPATE IN RESEARCH

PLACE PATIENT IDENTIFICATION LABEL HERE

DATE:

Patient Name:	APPROVAL

CAMC Health Education and Research Institute, Inc.
Center for Health Services and Outcomes Research
3200 MacCorkle Avenue, S.E.
Charleston, WV 25304

RESEARCH INFORMATION AND CONSENT FORM

Study Title: Pregabalin vs. Gabapentin on Reducing Opioid Usage in Trauma Patients

Protocol No.: **20-718**

Sponsor: MAIER Foundation and West Virginia Clinical and Translation Science Institute

Investigator: **Wes Kafka, PharmD., BCCP, MBA**

Phone #: **(304) 388-6286**

Statement that "you" refers to the study subject.
Throughout this consent "you" refers to the study subject. This consent form may have words you do not understand. Please ask the study doctor or the study staff to explain any words or information you do not clearly understand.

INVITATION TO PARTICIPATE
You are being asked to take part in this research study to test the effectiveness of using pregabalin (Lyrica) or gabapentin (Neurontin) in combination with traditional opioid pain medications in order to decrease the amount of opioid usage in trauma patients.

Before you agree to join in this study, you need to know the risks and benefits so you can make an informed decision. This is known as "informed consent". This consent form tells you about the study. Please read the information carefully and discuss it with anyone if you want. This may include a friend or a relative. If you have questions, please ask the study doctor or study staff to answer them.

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Your participation in this study is completely up to you. Research studies include only people who choose to take part. If you decide to participate, you are free to stop your participation at any time. Please take your time to make your decision.

WHY IS THIS STUDY BEING DONE?

Trauma introduces acute pain as well as chronic pain into the lives of its victims. Opioids were used traditionally to control pain in trauma patients. However, opioids usage have related risks and possible complications. This study plans to determine if adding pregabalin or gabapentin upon admission will reduce opioid usage in trauma patients. Pregabalin and gabapentin are two drugs that have been used for years to treat seizures, nerve pain, and anxiety and new research has shown their effectiveness in pre- and post-operative pain management. The study aims to compare patients receiving pregabalin vs. gabapentin vs. neither, and to determine daily average opioid requirement up to 7 days following initiation of study medication.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

A total of 210 patients will be enrolled in the study and divided over three groups.

Group A (70 subjects): Patients in this group will be started on Gabapentin upon admission.

Group B (70 subjects): Patients in this group will be started on Pregabalin upon admission.

Group C (70 subjects): Patients in this group will be neither on Gabapentin nor Pregabalin upon admission.

HOW LONG WILL YOU BE IN THE STUDY?

If you accept to participate in the study, you will be enrolled for 7 days or until discharge (if discharge was earlier than 7 days). Your medical records for that period of time will be reviewed to get medication list and doses, injury list, demographics, and outcomes from your hospitalization.

DO YOU HAVE TO PARTICIPATE?

No, your participation is voluntary. You may decide not to participate at all or, if you start the study, you may withdraw at any time. Withdrawal or refusing to participate will not affect your relationship with CAMC or the care received in anyway. If you agree to participate, you will receive a copy of this form.

WHAT IS INVOLVED IN THIS STUDY?

If you are interested in participating in the study, a research staff member will discuss with you and answer any of your questions. If you decided to participate in the study, the research member of the study team will discuss the details of the consent form and privacy forms and obtain your signatures. You may refuse to participate or may discontinue participation at any time during the entire duration of the study without penalty or loss of benefits to which you are otherwise entitled.

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If you agree to participate in the study, you will be randomized to one of the study groups. A member of the research team will open a numbered envelope to determine the specific treatment strategy. You will be told which medication the physician will be using and the dosage.

WHAT ARE THE RISKS?

Both pregabalin and gabapentin have potential side effects. The risk will be minimal as all patients who receive these drugs are followed closely by pharmacists, doctors, and other providers.

Adverse Reactions:

Gabapentin (Neurontin)	Pregabalin (Lyrica)
Occasional (10 to 20% chance of happening)	**Occasional (10 to 20% chance of happening)**
Somnolence "sleepiness or drowsiness"	Dizziness
Dizziness	Somnolence "sleepiness or drowsiness"
Ataxia "Impaired balance or muscles coordination"	**Less Often (1 to 10% chance of happening)**
Fatigue	Fatigue
Less Often (1 to 10% chance of happening)	Vertigo "spinning sensation"
Nystagmus "involuntary repetitive eye movement"	Ataxia "Impaired balance or muscles coordination"
Tremor "shaking movement in a part of the body"	Abnormal change in mood
Visual disturbances	Amnesia "partial or total loss of memory"
Amnesia "partial or total loss of memory"	Tremor "shaking movement in a part of the body"
Abnormal change in mood	Peripheral edema "swelling of legs or hands"
Peripheral edema "swelling of legs or hands"	Hypotension "low blood pressure"
Hypotension "low blood pressure"	Dry mouth
Diarrhea	Constipation
Dyspepsia "bloating, gassiness, or feeling full after eating"	Flatulence "gassiness"
Rhinitis "Irritation and swelling of the nose"	Myalgia "muscles soreness and achiness"
Rare (<1% chance of happening)	Dyspnea "breathing difficulties"
Suicidal thoughts	**Rare (<1% chance of happening)**
Decreased respiratory drive	Suicidal thoughts

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

Depending on study's outcomes, you may or may not benefit directly from participating in the study. However, the medical community may benefit from an increased understanding of the use to gabapentin and pregabalin in pain control regimen in trauma patients. Opioids have related risks of overdosing, poisoning, and tolerance and reducing the amount used to reach an adequate pain control can reduce complications and adverse events. That could result in fewer hospitalizations, lower overall costs, and better patient satisfaction and pain management to future patients.

WHAT OTHER OPTIONS ARE THERE?

Please understand that participation is completely voluntary. Your decision whether or not to participate will in no way affect your current or future relationship with your attending physicians, residents, or staff at Charleston

Area Medical Center (CAMC). You have the right to withdraw from the research at any time without penalty. You also have the right to refuse to answer any question(s) for any reason, without penalty. If you choose not to participate in the study, you will receive the standard of treatment for your pain at the discretion of your physician.

WHAT ABOUT CONFIDENTIALITY?

Any information about you obtained as a result of participation in this study will be kept confidential as legally as possible. If results of this study are published, you will not be identified. Your research records, just like hospital records, may be subpoenaed by court order or may be reviewed by medical personnel associated with the study and portions may be reviewed by federal regulatory authorities including the Food and Drug Administration, and the CAMC/WVU Charleston Division Institutional Review Board.

WHAT ARE THE COSTS?

You, your insurance company or Medicare will need to pay for all costs associated with your hospital stay. You will not be charged any additional fees for your participation in this study. The study medication's cost is considered a standard treatment and will be billed as normal.

WILL YOU GET PAID FOR PARTICIPATING?

You will not be paid for your participation in this study.

WHAT HAPPENS IF YOU ARE INJURED?

In the case of injury or illness resulting from this study, emergency medical treatment is available from Charleston Area Medical Center (CAMC).

The fact that you are voluntarily participating in this research study does not guarantee you will receive monetary compensation or payment for the costs associated with research-caused side effects or complications.

For more information concerning this research study and related risks or injuries, you may talk with your study doctor at telephone number **(304) 388-6286** or research member at telephone number **(304) 388-7808.** Signing this consent form does not waive or limit your legal rights.

CAN YOU BE REMOVED FROM THE STUDY?

For your safety, your study doctor may remove you from the study at any time without your consent.

WHAT IF YOU CHANGE YOUR MIND - CAN YOU STOP PARTICIPATING?

You may choose to stop participating at any time. No one will be mad at you and you will continue to receive care. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop for any reason, it is important to let your study doctor know as soon as possible so you can stop safely. You are free to seek care from a doctor of your choice at any time.

NEW INFORMATION

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You will be told of any important new information that is learned during the course of the study that may affect your health, welfare, or willingness to stay in this study.

CLINICAL TRIAL REGISTRY

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS?

For more information concerning this particular research and research-related risks or injuries, you can talk with **Wes Kafka, PharmD.**, principal investigator, at telephone number **(304) 388-6286** or a trauma research member at telephone number **(304) 388-7808.** In addition, if you have questions about your rights as a participant of this study, you may contact the Office of Research Compliance at **(304) 388-9913**.

VOLUNTARY CONSENT TO PARTICPATE IN RESEARCH

I have read, or have had read to me, all of the above. I have asked questions and received answers concerning areas I did not understand. With my signature below, I indicate that I willingly give my consent to participate in this study.

SIGNATURE (Required as written)

_____

Signature of participant OR participant's legal authorized representative / State relationship Date

_____

Signature of person obtaining or verifying consent Date

_____

Witness Signature Date

(A witness signature is only required if the consent form is to be read to the subject. In all other instances the witness signature should be left blank.)

IRB NUMBER: 20-718
IRB APPROVAL DATE: 10/16/2023
IRB EXPIRATION DATE: 10/15/2024

CAMC Health Education and Research Institute, Inc. (CHERI)
Charleston, West Virginia

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CAMC / WVU-CHARLESTON DIVISION INSTITUTIONAL REVIEW BOARD HIPAA AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

Note: The privacy law, Health Insurance Portability and Accountability Act (HIPAA), protects your individually identifiable health information. Protected health information or PHI is defined as individually identifiable health information transmitted or maintained in any form (electronic means, on paper, or through oral communication) that relates to the past, present or future physical or mental health or conditions of an individual. The privacy law requires you to sign an ***Authorization*** (or agreement) in order for researchers to be able to use and/or disclose your protected health information.

Study Information

Principal Investigator: **Wes Kafka, PharmD., BCCP, MBA**
Study Title: **Pregabalin vs. Gabapentin on Reducing Opioid Usage in Trauma Patients**

Authorization

You authorize **Wes Kafka, PharmD.** and his/her research staff to use and disclose your protected health information for research purposes in the study entitled referenced above. You also permit your doctors and other health care providers to disclose your protected health information for the purposes described below.

Your protected health information that may be used and disclosed includes:
Demographics, urine and drug screen, admitting injury list, length of stay, pre-existing (home) opioid analgesic regimens, inpatient opioid exposure prior to enrollment (up to 7 days after enrollment), surgery date and surgery performed, pain scores for each 24-hour period post-enrollment, post-enrollment complications, basic Metabolic Panel, and side effects.

Your protected health information will be used to:
To compare patients receiving pregabalin vs. gabapentin vs. neither, and to define daily average opioid requirement up to 7 days following initiation of study medication and determine if adding pregabalin or gabapentin upon admission will reduce opioid usage in trauma patients.

The Researchers may use and share your protected health information with:

- The CAMC/WVU-Charleston Division Institutional Review Board and/or the CAMC Health Education and Research Institute, Inc. ("CHERI") Research Administration Office, and the Office of Grants Development and Compliance.
- Federal regulatory authorities such as the FDA, USDA, OHRP, DHHS, etc.
- Charleston Area Medical Center, Inc., CHERI, or West Virginia University-Charleston Division employees directly

The researchers and MAIER Foundation and West Virginia Clinical and Translation Science Institute agree to protect your health information by using and disclosing it only as permitted in this Authorization and as directed by state and federal law.
You understand that once your protected health information has been disclosed to a third party, federal privacy laws may not protect it from further disclosure.
You understand that this Authorization does not prevent you from voluntarily disclosing your protected health information.
You understand that you, too, are responsible for protecting your health information.

You do not have to sign this Authorization.
If you decide not to sign the Authorization:
1. It will not affect your treatment, payment or enrollment in any health plan or affect your eligibility to receive benefits.
2. You will not be allowed to participate in the research study.

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After signing the Authorization

You can change your mind and:

1. Withdraw or revoke the Authorization and not let the researcher use or disclose further health information.
2. If you revoke the Authorization, you will send a written letter to **Wes Kafka, PharmD.** ***501 Morris St, Charleston, WV 25301*** to inform him/her of your decision.
3. If you revoke the Authorization, researchers may only use and disclose the protected health information already collected for this research study.
4. If you revoke the Authorization, your protected health information may still be used and disclosed should you have an adverse or unanticipated event.
5. If you revoke the Authorization, you will not be allowed to continue to participate in the research study.

Your Right to Access PHI and your study data:

Your Personal Health Information (PHI) is information about you that could be used to identify you, such as your name, address, telephone number, photograph, date of birth, social security number, new and existing medical records, or the types, dates and results of various tests and procedures. This may include information in your medical record and information created or collected during the study including for the creation and maintenance of a research database or repository.

You understand that you have a right to access your own protected health information held by the researchers.

You understand that your protected health information data collected for this study will be destroyed at the conclusion of data analysis for the study.

Authorization Expiration:

This authorization expires: *At the conclusion of the research study (projected study end date December 2027)*
If you have questions or concerns about your privacy rights: Contact the Privacy Office at (304) 388-1187. You may also request a copy of the Notice of Privacy Practices.

Signature

You are the research subject or are duly authorized to act on behalf of the research subject. You have read this information and will receive a copy of this form after it is signed.

_____ _____
Signature of Research Participant or Legal Representative Date

*Must explain relationship and responsibility to subject below

_____

*Printed Name of Above: _____