Ketamine: its effects on suicidal ideations and inpatient hospital length of stay.

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CONSENT TO PARTICIPATE IN RESEARCH

The University of Mississippi Medical Center

Study Title: Ketamine: its effects on suicidal ideations and inpatient hospital length of stay

Principal Investigator: Allen Richert, MD

Introduction

You are being invited to be in this experimental research study because you have been admitted to the hospital for thoughts of suicide. Please take your time making a decision and feel free to discuss it with your friends and family. Before agreeing to take part in this research study, it is important that you read and understand this document that describes the study. Please ask the study researcher or the study staff to explain any words or information that you do not clearly understand.

Purpose

Previous research studies have shown the drug ketamine can improve suicidal thoughts. Ketamine is a drug used for pain control, but is not approved for the treatment of depression or suicidal thoughts. We are doing this study to learn about ketamine and its effects on depression and thoughts of suicide. We also hope to learn if the drug affects the length of the hospital stay.

Procedures

If you agree to participate in this study, your participation will begin within 24 hours of being admitted to the hospital. After a member of the study team ensures that you understand the risks and benefits of participating versus not participating, you will be assigned, by chance, to one of the following groups:

- Group A: receives ketamine intravenous (IV) infusion over 45 minutes

- Group B: receives saline (salt solution) over 45 minutes

After receiving your infusion, you will be monitored for an additional 30 minutes by medical personnel in either the Post-Anesthesia Care Unit (PACU) or Short Stay Procedure Area (SSPA). Neither you, nor your study doctor, will know what group you are in. While receiving the infusion, your vital signs (including heart rate, heart rhythm, blood pressure, respiratory rate, and temperature) will be monitored on an anesthesia paper chart. After you are discharged from the hospital, the treatment team will analyze your medical record and compare the length of your hospital stay with others who participated in the study. The only information about your hospital stay that will be analyzed will be the length of your hospital stay.

If you are a woman of childbearing age, a urine pregnancy test will be performed after you agree to enroll in the study. All participants will also require an EKG. The cost of these tests will be covered by the University of Mississippi Departments of Anesthesiology and Psychiatry. If you are found to be pregnant or to have an abnormal heart rhythm, you will not be able to participate in the study.

Length of Participation

Your participation in this study will last until you are discharged from the hospital. You will receive a phone call three months after discharge, and again at six months after discharge to assess for any adverse medication reactions.

Risks of Ketamine

Less Likely:

- High blood pressure which may cause heart attack or stroke
- Racing heart beat
- Double vision
- Hallucinations
- Confusion

Rare:

- Slowed heart beat
- Throat spasms
- Low blood pressure
- Allergic reaction which may cause rash or shortness of breath
- Increased pressure in the eye which may cause vision changes
- Pressure in the space between the brain and the skull which may lead to headaches, nausea/vomiting, and vision changes

We do not know how your body might respond to the medications used in this study. We will discuss the risks identified above with you and the chances that they will happen. There may be risks that we do not know about at this time. Unknown problems, ranging from a mild inconvenience to some severe enough to cause stroke or heart attack may occur. If you experience any of the above-mentioned symptoms, please call the University of Mississippi Medical Center at 601-984-1001 and ask for Dr. Allen Richert, the principal investigator, or the person on-call for him.

Pregnancy

You may not be pregnant, trying to become pregnant, or breastfeeding a baby while taking part in this research study. Urine pregnancy tests will be done on all women of childbearing potential.

Benefits

You may or may not receive a direct benefit from being in this research study. Previous studies have shown that ketamine may improve depression and suicidal thoughts, and therefore shorten the length of hospital stay. However, there may not be any difference at all in your situation. We hope to learn information that may help others in the future.

Alternatives

The alternative is not to participate. The study drug is experimental. This means you can only receive it by enrolling in this study.

Costs

There will not be additional costs to you if you participate in this study. University of Mississippi Medical Center Departments of Anesthesiology and Psychiatry will supply the study drug, EKG, and urine pregnancy test (if applicable) at no cost to you. Insurance companies and other third party payers will not be billed for research procedures.

The medical care that you will receive while in this study is considered standard care for your situation and would be recommended whether or not you participate in this study. These costs will be billed to you or your insurance carrier.

Research-related injury

In the case of injury or illness resulting from your participation in this study, medical treatment is available to you at the University of Mississippi Medical Center. You will be charged the usual and customary charges for any such treatment you receive.

Compensation

You will not be paid for participating in this study.

Voluntary Participation

Your participation is voluntary. If you decide not to participate in this study you will not suffer a penalty or loss of benefits to which you are otherwise entitled.

Withdrawal

You may choose to stop your participation in this study at any time. If you decide to withdraw the information already collected about you may still be used in this study but additional information will not be collected. Your decision to stop your participation will have no effect on the quality of medical care you receive at the University of Mississippi Medical Center. Please talk to us about this decision to help ensure your safe withdrawal from the study.

New Information

You will be told of any information we learn during your participation in this study that may affect your willingness to participate.

Confidentiality

Every effort will be made to keep the information we learn about you private. Study personnel, the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), the University of Mississippi Medical Center's Institutional Review Board (IRB) and Office of Integrity and Compliance may review the study records. If study results are published your name will not be used.

A copy of this informed consent document will be filed in your medical record because the experimental research you are agreeing to participate in involves your care, diagnosis, or treatment.

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.

Protected Health Information

Protected health information is any personal health information through which you can be identified. The information collected in this study will be the type of infusion you receive, your medical record number, and the length of your hospitalization. Your name, age, and date of birth will not be recorded. By signing this consent document, you authorize Dr. Richert to collect this information and use your records as necessary for this study.

The information collected for this study will be kept indefinitely and may be combined with information collected through other research studies or used in other studies but no information will identify you.

You have the right to cancel this authorization at any time by providing Dr. Richert with a written request to cancel the authorization. If you cancel this authorization, medical information and records about you that were created before the authorization was cancelled will still be used and disclosed as needed to preserve the integrity of the study.

This authorization has no expiration date. If you do not sign this consent document, you will not be allowed to participate in this study.

Number of Participants

We expect 100 participants to enroll in this study here at the University of Mississippi Medical Center.

Questions

If you have questions about this study or need to report any problems, side effects, or injuries, please call the call the University of Mississippi Medical Center at 601-984-1001 and ask to be connected to Dr. Allen Richert, the principal investigator, or the person on-call for him.

You may discuss your rights as a research participant with the Chairman of the University of Mississippi Medical Center's Institutional Review Board, 2500 North State Street, Jackson, Mississippi, 39216; telephone: 601-984-2815; facsimile, 601-984-2961. The Institutional Review Board is a group of people not involved with this study who have reviewed the study to protect your rights.

You will be given a copy of this consent document after it has been signed.

Statement of Participation

I have been told about this study, including the experimental treatment I will receive, and the possible risks and benefits. I agree to participate in this

study, to follow instructions, and to report any side effects to my study doctor. My participation is voluntary and I may withdraw at any time without any penalty or loss of benefits to which I am entitled, including medical care at the University of Mississippi Medical Center.

By signing this form, I am not giving up any legal rights I may have.

_____
Participant's Printed Name

_____
Participant's Signature

_____
Date

_____
Printed Name of Legally Authorized Representative and relationship to participant (if applicable)

_____
Signature of Legally Authorized Representative (if applicable)

_____
Date

_____
Printed Name of Person Obtaining Consent

_____
Signature of Person Obtaining Consent

_____
Date

I acknowledge that the participant identified above has been entered into this study, with properly obtained informed consent.

_____
Signature of Principal Investigator

_____
Date