NORTH MEMORIAL HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: *Low Dose Ketamine for Blunt Thoracic Trauma*

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What you should know about this study:

This is a clinical research study. Your study doctor or a trained provider from the North Memorial Acute Care Surgery Department will explain the study to you.

Research studies include only people who volunteer, or choose, to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you have 3 or more broken ribs.

Why is this study being done?

The purpose of this study is to see if adding the drug ketamine to usual therapy treats the pain from broken ribs better than standard medications. In this study, you will get an intravenous (IV) infusion that includes either ketamine or saline. You will not get both. Adding ketamine to the usual treatments for broken ribs may decrease pain and improve lung function.

Intravenous (IV) infusion is when liquid medicine given through your vein using a needle attached to a tube. Saline is a commonly used fluid given through an IV for hydration and to help administer medication.

How long will I be in the study?

You will receive either the study medication or a placebo by a continuous infusion through an intravenous (IV) catheter for 48 hours (2 days). Before, during, and after the study you will receive the standard care for broken ribs at North Memorial.

How many people will take part in this study?

About 50 people will take part in this study. 25 study subjects will receive an infusion of ketamine and 25 will get saline infusion.

What will happen if I take part in this research study?

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in any group.

- If you are in group 1 you will receive an intravenous fluid infusion that contains ketamine dissolved in saline.
- If you are in group 2 you will receive an intravenous fluid infusion that contains only saline (**placebo**).
- You will receive all of the standard therapies and medications for treatment of broken ribs regardless of whether you are assigned to group 1 or group 2.

Before you begin the main part of the study...

You will need to have the following exams, tests or procedures to find out if you can be in the main part of the study. These exams, tests or procedures are part of regular care.

- Physical examination by Emergency Medicine and Trauma doctors
- X-ray studies to determine if you have broken ribs and how many broken ribs you have.

During the main part of the study...

If the exams, tests and procedures show that you have more than 3 broken ribs and you choose to take part, then you will need the following tests and procedures. They are part of regular clinical care.

- X-ray studies to examine your lungs
- Tests to see how well your lungs are functioning
- Monitoring the amount of oxygen in your blood stream
- Questions about how much pain you are having
- Other tests or procedures that your doctors feel are needed for evaluation or treatment of other injuries or conditions.

When you are finished receiving 48 hours of infusion of the study drug solution...

The continuous intravenous drug **(ketamine)** or saline infusion will be stopped and disconnected. Your doctor will determine whether or not to continue intravenous fluids and/or medications **(saline, pain medications, antibiotics, etc)**. You will continue to receive all standard care for multiple broken ribs. Your doctors and nurses will decide when you can be discharged from the hospital.

Where will the study take place?

All study procedures will be done in the Trauma Surgical ICU (5SW) and the inpatient trauma unit (6W) at North Memorial Health Hospital in Robbinsdale, MN.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side affects you experience while taking part in the study.

Risks and side effects related to use of ketamine include those which are:

Common (~90%)

- Most patients do not have side effects from ketamine

Less Common (≥10%)

- Neurologic symptoms seen with recovery from anesthesia, including confusion, dream-like states, excitement, irrational behavior, hallucinations, and vivid imagery.

Rare (<10%)

- serious, potentially life-threatening allergic reaction
- elevated pressure around the brain
- elevated pressure within the eye
- elevated blood pressure
- rapid or irregular heart rate

Unknown Risks: The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

- For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While doctors hope adding ketamine to the standard medications used to treat rib fractures will improve pain control and decrease the need for narcotics **(narcotics are strong pain relievers such as oxycodone, morphine, or fentanyl, which can be addictive and are intended for short-term use).**

If pain is better controlled there may also be improved lung function and faster recovery. There is no proof that this will occur. We do know that the information from this study will help doctors learn more about ketamine as a treatment for pain associated with multiple broken ribs. This information could help future trauma patients.

What other choices do I have if I do not take part in this study?

If you decide not to participate in this study you will receive the standard treatment for multiple broken ribs at North Memorial Health Hospital.

How will information about me be kept confidential?

We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Study subjects will get a study number when they are enrolled in the study. Once the study is over your medical information will only be identified by your study number. Your medical information may be used in future research studies, but this would not include any private health information.

Some information from your medical records will be collected and used for this study. Your signed consent form and some of your research tests will be added to your North Memorial Health medical record. Therefore, people who can see your health records may find out that you were in this study. Your personal information may be given out if required by law. Your name and personal information will not be used if this study is published or presented at scientific meetings.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of North Memorial Health

Will any research-related procedures be billed to me?

Two types of procedures will be done during this study. You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any medications or procedures done only for research will not be charged to you or your insurer.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Michaela West, MD if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call them at 763-581-3717. If you are injured as a result of being in this study, North Memorial Health will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by North Memorial Health depending on a number of factors. North Memorial Health and the study sponsor do not normally provide any other form

of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 763-520-5353. The IRB is a group of individuals designated by the hospital under federal law to approve research studies. The North Memorial IRB monitors research related rights and safety of study subjects at North Memorial Medical Center

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor(s) Michaela West, MD at 763-581-3717.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 763-520-5353.

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.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____ _____

Date Participant's Signature for Consent

_____ _____

Date Person Obtaining Consent