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November 2022

To Whom it may Concern,

This is a copy of the consent form for the clinical trial registered under NCT04562779. This is the latest version, which was approved April 26, 2021. It underwent 'Continuing Review' with no changes in August 2021 and August 2022.

Sincerely,

Dale Terasaki, MD MPH
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Denver Health & Hospital Authority
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Principal Investigator: Dale Terasaki
COMIRB No: 20-2008
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Study Title: Single-dose interventions to reduce re-admissions for hospitalized patients with refractory alcohol use disorder: A randomized pilot feasibility study.

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

Continued alcohol use has been shown to cause many serious medical conditions and increase chances of being admitted to the hospital. We want to find ways to help you drink less alcohol and decrease your chances of being admitted to the hospital. Naltrexone (as an injection) and ketamine (as an infusion) are two medicines that may help decrease alcohol use, and we are looking at ways to provide these treatments in the hospital. We are also looking at ways to help you connect with outpatient addiction treatment to give you the best chance of staying in recovery.

You are being asked to be in this research study because 1) you are between 18 to 65 years of age with a diagnosis of severe alcohol use disorder recorded during your current admission; 2) you have had one or more alcohol-related admissions OR two or more alcohol-related emergency department visits in the past year; 3) you have insurance; and 4) you have been seen for an addiction consult.
Up to 60 people will participate in the study.

Other people in this study

Up to 60 people from your area will participate in the study.

What happens if I join this study?

If you join the study, you will be randomly assigned to one of three groups. The first group will receive an intramuscular (IM) injection of a medicine called naltrexone before leaving the hospital. The second group will receive an intravenous (IV) infusion of a medicine called ketamine before leaving the hospital. Both medicines may decrease alcohol use for some people. The third group will receive neither of the medicines. All of the groups will be assisted in connecting with our outpatient addiction clinic.

Because we are looking at the effects of these medicines, you will not be prescribed other medicines that specifically treat alcohol use disorder on discharge. However, you might be prescribed a medicine for alcohol use at follow-up, within a week of being discharged.

You will be asked to complete several questionnaires and submit one or more urine samples and one or more blood tests during your participation in this study. These tests are a part of usual clinical care.

We will check your electronic health record multiple times during the study, which may reveal hospital admissions and emergency department visits at Denver Health and other hospitals. This will help us to record whether you had a re-admission within 30 days of discharge. If you are re-admitted there will be no consequences from being in this study.

Your participation in the study will last for up to 30 days after you are discharged from the hospital.

What are the possible discomforts or risks?

Discomforts you may experience while in this study depend on which group you are assigned to.

If you are in the injection naltrexone group, you may experience minimal pain and discomfort at the injection site (on the thigh or buttock), nausea, decreased appetite, and fatigue. You may risk opioid withdrawal if you are currently taking opioids, but we are only accepting patients who are not taking opioids. More serious risks include liver inflammation, infection, blood clot, bleeding, and/or allergic reaction, though these are very rare.

If you are in the intravenous ketamine group, possible risks include discomfort at the intravenous catheter site, unpleasant out-of-body experiences or anxiety, and high blood pressure which could result in stress on your heart, but we are only including patients that are low risk for these problems. There is also the risk of developing an addiction to ketamine after discharge, but this is very unlikely based on other research studies.

A possible risk among all groups is having unpleasant memories or emotions that come up as a result of answering questions and engaging in treatment. Also, we will be gathering data from your medical record, which means there is a very small risk that your identity would become known to people outside of the research study. We are taking every feasible step to make sure that does not happen.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it can not be guaranteed.

We do not know if either of the medicines have a negative effect on pregnancy. We are only including people in the study who are not pregnant. However, if you do become pregnant within a month of your discharge, please let us know and we can provide guidance.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

By participating in this study, you may benefit from decreasing your alcohol use, decreasing the likelihood of developing serious medical conditions and decreasing your likelihood of being admitted to the hospital again. Also, you will be benefiting others by contributing to the research on treatment of alcohol use disorder.

Are there alternative treatments?

The current standard of care for alcohol use disorder in the hospital includes the offer of medications (typically oral naltrexone) and an addiction medicine consultation which can also result in referral to the Substance Use Disorder clinic or other treatment program.

There may be other ways of treating your alcohol use disorders. You could also choose to get no treatment at all.

You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

This research is funded by a small grant from the hospital (Denver Health).

Will I be paid for being in the study?

You will be paid $10.00 at the time of study enrollment and $20.00 at the follow-up visit. This will add up to a total of $30.00 if you complete both visits. If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

It is important to know that payments for participation in a study is taxable income.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should reach out to Dr. Dale Terasaki immediately. His office phone number is 303-602-6922 and his email address is dale.terasaki@cuanschutz.edu.

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Dale Terasaki. You may ask any questions you have now. If you have questions later, you may call Dr. Terasaki at 303-602-6922 (office) or e-mail at dale.terasaki@cuanschutz.edu
You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Terasaki with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

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.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- Denver Health and Hospital Authority

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Dale Terasaki
777 Bannock Street
Denver, CO, 80204
e-mail: dale.terasaki@cuanschutz.edu

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research
- The study doctor and the rest of the study team.
- Denver Health, who is the organization paying for this research study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory studies, and hospital encounters
- Research Visit and Research Test records
- Psychological and mental health tests
- Alcoholism, Alcohol or Drug abuse
- Billing or financial information

What happens to Data, Blood and Specimens that are collected in this study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data and other specimens given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data and other specimens collected from you.
- If data or other specimens are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name:_____

A signature of a witness is required for consent of non-reading subjects and consent using a short form.

Witness Signature: _____ Date:_____

Print Name:_____

Witness of Signature ϒ
Witness of consent process ϒ