



ADULT CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Understanding the Differences between Ketamine Treatment Plans for Chronic Conditions

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Study Purpose

The purpose of this study is to observe ketamine treatments in use with chronic conditions.

Pay to Participate

The study is a pay-to-participate study. The initial cost for entering the study is \$495.00, including the medication for six to twenty treatments. Additional treatments during the three-month treatment may be provided at the cost of medication plus processing fees. The cost for refills may range between \$150 and \$200. Requirement incentives may be provided.

Further, a sliding scale will be developed that will reduce bias. The researchers will seek outside donations to help lower the costs. The most compelling reason for proposing a pay-to-participate trial is the difficulty in securing funds through traditional government and industry mechanisms. When research cannot secure funding through traditional mechanisms, investigators may ask research subjects to shoulder the burden, in whole or in part. The federal government funds research through a competitive process that aims to allocate public research dollars to projects designated as the highest priority.

Many proposed studies will not secure government funding, sometimes because they are low quality but often because there is simply not enough money to fund all worthwhile projects. On the industry side, the development costs of an investigational drug or device may be prohibitive to the conduct of a clinical trial, absent charging for an investigational product.

Number Of Study Participants

If you decide to be in this study, you will be one of a minimum of 50 people in this research study.

Duration Of Study

Your participation will involve a minimum of three months and could be longer.

Procedures

If you agree to be in the study, we will ask you to do the following things:

1. Participate in all appointments as scheduled.

2. Complete a medication diary of all medications (include over the counter) the diary will include information will include: Date, Time, Method of Delivery, and Dose.
3. Complete the psychological evaluations such as
 - i. Brief Pain Inventory (B.P.I.; Cleeland, 1991)
 - ii. Patient Health Questionnaire for Depression (PHQ-9; Kroenke, Spitzer, & Williams, 2001)
 - iii. Generalized Anxiety Disorder 7-Item (GAD-7; Spitzer, Kroenke, Williams, & Lowe, 2006)
 - iv. Deliberate Self-Harm Inventory (D.S.H.I.; Gratz, 2001)
 - v. Suicidal Ideation Attributes Scale (S.I.D.A.S.; van Spikjer et al., 2014)
 - vi. The Columbia Suicide Severity Rating Scale (C-SSRS)

Risks And/Or Discomforts

Ketamine is a dissociative anesthetic developed in 1963 and currently used as an anesthetic on humans. It is also widely used in veterinary medicine. It is also sold on the street, typically once it has been stolen from veterinarians' offices. Taking this drug can produce several side effects, some more dangerous than others but nonetheless requiring medical attention. Euphoria and hallucinations are common ketamine side effects. Some of the ketamine side effects are psychological feelings:

- Euphoria
- Knowing what you want to say but the inability to say it out loud, similar to aphasia
- Bad dreams or nightmares
- Loss of attention span
- Inability to exercise good judgment
- Hallucinating

Ketamine tends to cause a wide variety of effects on almost every area of the body. In the stomach, it can cause severe abdominal pain. While on ketamine, you can easily injure yourself and not even realize it due to the fact it is an anesthetic. Your lack of response to pain while under the influence can lead to

a much more extensive injury. Unfortunately, if you can't feel the pain, you don't realize you have been injured therefore, if you hurt your knee, you might continue to walk around pain-free while under the influence of the drug. In the end, you might have pulled or torn more ligaments or, worse, walking on it because you never felt the pain of your injury.

Ketamine also causes long-term damage to the bladder and urinary tract. The use of ketamine can cause thickening in the walls of these organs, even getting to the point where the person is unable to urinate. Being unable to urinate can then lead to long-term damage to the bladder. It can also cause severe kidney issues as the drug begins leaving the body. If it is mixed with amphetamines, the combination can cause extremely high blood pressure. The longer a person abuses ketamine, the longer the effects will be felt. It can take a year or longer to get one's system back to a normal state. The longer a person uses ketamine, the longer the effects will be felt. It can take a year or longer to get one's system back to a normal state. Unfortunately, for some people, the more serious side effects, such as memory loss and brain damage, may end up being permanent, and as with the use of almost any drug, death is always a possibility.

Benefits

The study has the following possible benefits for you. Please feel free to get a free copy of the ebook written by the RIVER program on ketamine. Go to www.riverofchange.org.

Alternatives

There are many commercially available ketamine clinics. Check your local area.

Confidentiality

The records of this study will be kept private and will be protected to the fullest extent provided by law. In any sort of report, we might publish, we will not include any information that will make it possible to identify you. Research records will be stored securely, and only the researcher will have access to the records.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by US 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.

Use Of Your Information

Identifiers about you will be removed from the identifiable private information, and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Medical Treatment

If you become ill or injured due to participating in this study, contact your regular medical provider. Your insurance company may or may not pay for these costs if you have insurance. You will be billed if you do not have insurance, or if your insurance company refuses to pay. Funds to compensate for pain, expenses, lost wages, and other damages caused by injury are not routinely available.

Right To Decline Or Withdraw

Your participation in this study is voluntary. You are free to participate in the study or withdraw your consent at any time during the study. You will not lose any benefits if you decide not to participate or if you quit the study early. The investigator reserves the right to remove you without your consent at such time that he/she feels it is in the best interest.

Researcher Contact Information

If you have any questions about the purpose, procedures, or any other issues relating to this research study, you may contact Dr. Frank Yurasek, M.D. at 6954 30th Street, Brewin IL 60402, USA, Email: info@riverofchange.org.

IRB Contact Information

If you would like to talk with someone about your rights of being a subject in this research study or about ethical issues with this research study, you may contact Ed Lesofski at 406-431-4890.

Participant Agreement

I have read the information in this consent form and agree to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. I understand that I will be given a copy of this form for my records.

Signature of Participant

Printed Name of Participant

Date _____