



INFORMED CONSENT FOR KETAMINE TREATMENT

NAME: _____

1. PROCEDURE – KETAMINE INFUSION THERAPY

An intravenous line (IV) will be started in an extremity (arm, hand, or leg) so you can receive ketamine. Your blood pressure, heart rate, and oxygen saturation will all be monitored throughout the infusion procedure under a physician or nurse practitioner supervision. You will be given a sub-anesthetic dose of ketamine, by slow continuous infusion. The duration of the infusion varies from 40 and 55 minutes for depression, and 2 to 4 hours for chronic pain. Depending upon your response to this first infusion, we may increase the dose incrementally with your subsequent infusions to maximize your response. We can also often adjust the infusion rate during each infusion, depending on how you are responding, to maximize the effectiveness of each infusion. Adjuvant medications may also be administered if necessary, such as anti-nausea medication.

2. RISKS/SIDE EFFECTS

Risk of ketamine: Side effects normally depend on the dose and how quickly the injection is given. The dose being used for this purpose is generally lower than anesthetic doses, and will be given by slow continuous infusion. Side effects are usually mild and often resolve on their own. The incidence of side effects is higher with more prolonged infusions.

Common side effects, greater than 1% and less than 10%:

- hallucinations
- vivid dreams
- nausea and vomiting
- dizziness
- blurred vision
- increased heart rate and blood pressure during the first half of the infusion
- out of body experience during the infusion

These symptoms typically dissipate when the infusion is stopped. You should not drive the day of an infusion and can resume driving the following day.

Patient initials _____

Uncommon side effects, greater than 0.1% and less than 1%:

- rash
- double vision
- pain and redness in the injection site
- Increased pressure in the eye
- jerky arm movements resembling a seizure

Rare side effects, greater than 0.01% and less than 0.1%:

- allergic reaction
- irregular or slow heart rate
- arrhythmia
- low blood pressure
- cystitis or other inflammation of the bladder
- Even more severe side effects up to and including death are possible, but extremely unlikely, such as a fatal allergic reaction to one of the medications.

Other Risks:

- Ketamine can cause various symptoms including but not limited to flashbacks, hallucinations, and feelings of unhappiness, restlessness, anxiety, insomnia and disorientation.
- The uncommon risk of a dosing error, or unknown drug interaction that may require medical intervention including intubation (putting in a breathing tube), or hospitalization.
- Starting an IV may cause temporary discomfort from the needle stick, bruising, or infection. Fainting may also occur.
- Risk of other medications interacting with ketamine. It is very important that you disclose all medications (both prescription and over the counter) and supplements that you are taking.
- Ketamine may not help your depression, bipolar disorder, PTSD, anxiety, other mental health condition, or chronic pain syndrome.

3. BENEFITS

Unlike conventional anti-depressants, ketamine has been associated with a rapid decrease in depression, bipolar, and PTSD symptoms. It has also been shown to be helpful with a variety of chronic pain syndromes, and with alleviating the cravings for drugs and alcohol. The initial series of infusions is used to prolong the longevity of improvement. While the goal is improvement of symptoms, results cannot be guaranteed, and there is no way to predict how any individual will respond to ketamine infusion therapy. These effects may not be long lasting, and will most likely require further infusions. Ketamine is not the only option for patients with treatment-resistant depression. There are other alternatives, including electroconvulsive shock therapy (ECT) and transcranial magnetic stimulation (TMS). Ketamine is not the only option for patients with chronic pain. Other alternatives include pain medicines, anticonvulsants, physical therapy, cognitive-behavioral therapy, steroid injections, spinal pumps, spinal cord stimulation, and surgery. Ketamine is also not the only option for alcohol and drug abuse.

4. WHAT SAFETY PRECAUTIONS MUST I TAKE?

- I will eat LIGHTLY before each of the infusions.
- I will NOT drive a car, operate hazardous equipment, or engage in hazardous activities for 24 hours after each treatment as reflexes may be slow or impaired. Another adult will need to drive me home.
- I will not conduct business or make any important decisions the remainder of the day after an infusion.
- I must refrain from alcohol or other substances prior to, and for 24 hours after an infusion.
- I must tell the clinic about all medications I am taking, especially narcotic pain relievers or barbiturates.
- If I experience a troublesome side effect after I leave the clinic, I should contact Georgia Renew Clinic or call my primary care provider, call 911, or go to my local emergency room.

5. IMPORTANT CAVEATS:

- KETAMINE INFUSION THERAPY IS NOT A COMPREHENSIVE TREATMENT FOR DEPRESSION, ANXIETY OR ANY PSYCHIATRIC SYMPTOMS; NOR FOR CHRONIC PAIN, NOR FOR DRUG AND ALCOHOL ABUSE. Your ketamine infusions are meant to augment (add on to, not be used in place of) a comprehensive treatment plan. We advise you to be (and agree to be) under the care of a qualified mental health professional (or an internal medicine or family physician with experience and skill in treating psychiatric illnesses) while receiving ketamine infusions, and for the duration of your psychiatric symptoms. Pain patients should be under the care of a pain management physician as well as a primary care provider - we provide ketamine infusions only, and do not diagnose or provide comprehensive pain management treatment INCLUDING the prescription of pain medications. Follow up medications may be suggested but these will be the responsibility of your treating physician.
- SPECIAL NOTE ON SUICIDAL IDEATION
Psychiatric illnesses (especially, depression), chronic pain, and addictions carry the risk of suicidal ideation (thoughts of ending one's life). Any such thoughts you may have now, at any time during the weeks of your ketamine infusions, or at any point in the future, which cannot immediately be addressed by visiting with a mental health professional should prompt you to seek emergency care at an ER or to call 911.
- KETAMINE USE DURING PREGNANCY OR BREAST FEEDING IS NOT GENERALLY RECOMMENDED

6. VOLUNTARY NATURE OF THE TREATMENT

You are free to choose to receive or not receive the ketamine infusion. Please tell the doctor if you do not wish to receive the infusion.

7. WITHDRAWAL OF TREATMENT

Your provider has the right to stop the infusion at any time. They can stop the infusion with or without your consent for any reason.

8. PATIENT CONSENT

I agree to maintain a relationship with my healthcare or an internal medicine or family physician while receiving ketamine infusions.

I agree to allow Georgia Renew Clinic to access all information pertaining to my mental healthcare and permission to speak to my mental healthcare provider to discuss my condition and the administration of Ketamine Infusion therapy.

I know that ketamine is not an FDA approved treatment for depression, bipolar disorder, or PTSD.

I know that my taking part in this procedure is my choice.

I know that I may decide not to take part or to withdraw from the procedure at any time.

I know that I can do this without penalty or loss of treatment to which I am entitled.

I also know that the doctor may stop the infusion without my consent.

I also know that ketamine infusion therapy may not help my depression, bipolar disorder, or PTSD.

I have had a chance to ask the doctor questions about this treatment, and those questions have been answered to my satisfaction.

The possible alternative methods of treatment, the risks involved, and the possibility of complications have been fully explained to me.

No guarantees or assurances have been made or given to me about the results that may be obtained.

I _____ consent to the treatment or procedure for the above services. I have been asked if I want more detailed explanation, but I am satisfied with the explanation and do not want more information.

PATIENT or person authorized to sign for patient

DATE SIGNED: _____

Witness signature _____