

INFORMED CONSENT FOR KETAMINE THERAPY

This consent form contains information about the use of subanesthetic ketamine therapy for the treatment of depression and other psychiatric illnesses. Ketamine has been approved by the Food and Drug Administration (FDA) for use as an anesthetic agent for many years. The use of ketamine in lower, subanesthetic doses to treat depression is a newer, off-label use of ketamine. It is usually used after other treatments have been unsuccessful. While ketamine is not formally approved by the FDA for this use, there are now many studies that demonstrate it may be an effective and rapid treatment option for multiple disorders including major depressive disorder, bipolar disorder, and substance use disorder. Benefits may occur after only one treatment, though typically an initial course of several treatments are required for a more robust response. If your depressive symptoms respond to this initial course of ketamine therapy, you may receive further treatments. It is recommended that you continue treatment with other medications and ongoing psychotherapy as ketamine therapy works best when part of an integrated treatment program.

CONTRAINDICATIONS TO KETAMINE THERAPY

Ketamine therapy should not be used in patients with the following:

- Active substance abuse
- History of increased intracranial pressure
- Uncontrolled high blood pressure
- Prior hypersensitivity or negative reaction to ketamine
- Psychosis
- Pregnancy or breastfeeding mother
- Untreated hyperthyroidism

OVERVIEW OF SUBANESTHETIC KETAMINE TREATMENT

Ketamine can be administered IM (intra-muscular) or IV. Your blood pressure, heart rate, and oxygen saturation will all be monitored throughout the administration under a physician's supervision. You will be given a subanesthetic dose of ketamine, by slow continuous IV infusion or IM. If given IV, 40 minutes for depression. Depending upon your response to this first administration, we may increase the dose incrementally with your subsequent treatments to maximize your response. We will 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, mild sedatives for agitation, etc.

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 lower than anesthetic doses. Side effects often go away on their own. The incidence of side effects is higher with more prolonged infusions.

- Impaired balance and coordination
- Headaches
- Blurred or double vision
- Confusion, excitability, anxiety
- Sense of time may be altered
- Nystagmus (rapid eye movements), rare
- Allergic reactions, rare
- Sleepiness
- Nausea or vomiting, loss of appetite
- Slurred speech
- Impaired ability to see, hear or feel things accurately
- Elevation of pulse or blood pressure
- Elevation of intraocular pressure (increased pressure in the eyes), rare

The altered state of consciousness produced by ketamine usually lasts approximately 30 minutes after administration but can last longer. The impaired sense of balance, dizziness, and possible nausea gradually subsides over three to six hours. Patients cannot drive themselves home after ketamine treatment.

-Because of the risk of nausea and vomiting, please refrain from eating and drinking for at least the 4 hours preceding the session. If you are unduly nauseated during treatment, you may be offered an anti-nausea medication.

-Ketamine can cause a significant increase in blood pressure or heart rate (pulse). If monitoring shows this has occurred, you may be offered medication to lower your blood pressure or heart rate.

-Agitation may occur during a ketamine session. If you are uncomfortable, you may be offered medication to help you relax.

-Chronic, high dose, recreational abuse of ketamine, can cause urinary tract symptoms and even permanent bladder dysfunction, though no significant effects have been reported with medical use. Risks of having an IV placed or IM administered:

- Mild discomfort at site of placement
- Bruising
- infection
- Fainting
- Bleeding

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 therapy. These effects may not be long lasting and will most likely require further treatment. 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.

IMPORTANT CAVEATS KETAMINE 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 treatments are meant to augment (add on to, not be used in place of) a comprehensive treatment plan. We advise you to be (and I 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 treatments, or at any point in the future, which cannot immediately be addressed by visiting with a mental health professional should you to seek emergency care at an ER or to call 911.

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 treatment.

WITHDRAWAL OF TREATMENT

Your doctor has the right to stop the administration at any time. They can stop the treatment with or without your consent for any reason.

CLINICAL POINTS

- Ketamine is commonly administered intravenously in the doses of 0.5mg/kg. However, benefits and adverse effects are probably dose, dependent in the range of 0.10-0.75 mg/kg.
- Ketamine may be administered as rapidly as in a bolus dose to as slowly as across 100 minutes, Sessions that are 40 minutes in duration are conventional, especially with intravenous dosing. Bolus administration is safe and effective when the drug is administered intramuscularly or subcutaneously.
- Ketamine is safe and effective when administered by oral, sublingual, transmucosal, intranasal, intravenous, intramuscular, and subcutaneous routes, Bioavailability is best when ketamine is administered parenterally or intranasally. Oral, subcutaneous, and intranasal delivery are perhaps the most practical methods.
- Ketamine sessions can be repeated (if necessary, at higher doses) to elicit response in patients who do not respond. Sessions can be repeated to extend and maintain response in those who do benefit. Repeated sessions at suitably spaced intervals have been described across weeks to years of treatment in refractory cases.

Table 1. Important Take-Home Messages on Dosing, Rate of Administration, Route of Administration, Duration of Treatment, and Frequency of Sessions When Ketamine Is Used in Subanesthetic Doses for the Treatment of Depression

1. Ketamine is most commonly dosed at 0.5 mg/kg. However, some patients may benefit from doses as low as 0.1 mg/kg. Patients who do not benefit at 0.5 mg/kg may respond at higher doses, such as 0.75 mg/kg. Higher doses may be associated with more adverse effects. These findings notwithstanding, parallel-group studies find no efficacy differences between different ketamine doses.
 2. Ketamine is usually dosed across 40 min, especially when the dosing is by the IV route. However, benefits have been described even when infusion sessions are as short as 2 min or as long as 100 min. Ketamine is administered as a bolus when treatment is by the IM or SC route. Tolerability does not appear to be compromised by shorter treatment sessions or by bolus administration. Whereas ketamine has also been administered in best tolerated doses as a continuous infusion across 4–5 days, the case for such prolonged treatment remains unestablished.
 3. Ketamine has been found effective when administered by oral, sublingual, transmucosal, intranasal, IV, IM, and SC routes. Whereas IV dosing has been the most extensively studied, intranasal, SC, and oral (despite low bioavailability) dosing are more convenient, but will require better study before they can be recommended over IV dosing.
 4. Ketamine dosing can be repeated once in 2–3 days for 4–6 treatment sessions if the initial session elicits inadequate response; later sessions can be dosed at the same level or (preferably) at higher levels.
 5. In patients in whom ketamine is required for continuation and maintenance therapy (because no other treatment is effective), sessions are best scheduled at an individualized frequency (typically once in 3–5 days) where each dose is administered a little before the effect of the previous dose wears off.
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Abbreviations: IM = intramuscular, IV = intravenous, SC = subcutaneous.



PATIENT CONSENT

I understand that I am to have no food or drink 4 hours prior to ketamine session.

I 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 symptom.

I agree to allow Addison Internal Medicine 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 therapy.

I understand that ketamine is not an FDA approved treatment for depression, bipolar disorder, or PTSD. I know that taking part in this procedure is my choice.

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

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

I understand that the doctor may stop the infusion or injection without my consent.

I understand that ketamine 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.

You should not sign this consent until you have spoken with the medical staff of Addison Internal Medicine about the procedure and have had all your questions answered including those about risks and alternatives.

Patient Consent: _____
Patient Signature

_____/_____/_____
First Name Last Name Date

PHYSICIAN STATEMENT I have carefully explained the nature of subanesthetic ketamine therapy to this patient. I hereby certify that to the best of my knowledge, the individual signing this consent form understands the nature, conditions, risks, and potential benefits involved in participating in ketamine therapy.

Signature

_____/_____/_____
First Name Last Name Date