

MOSAIC

INFUSIONS & WELLNESS

Informed Consent For Ketamine Infusion Therapy

Prior to consenting to ketamine infusion therapy, it is important for you to understand any potential risks and potential benefits of the procedure. Read this information closely and discuss it with family and friends as you wish. Ask your provider if you have any questions, if something is not clear to you, or if you wish to seek more details about the procedure. Your signature on this document will reflect that you have received all the information below and you were able to receive answers to any questions or concerns you had with your provider prior to undergoing this procedure.

Ketamine was approved by the FDA in 1970 for anesthesia and for sedation during medical procedures. Since its approval, Ketamine has been widely used in operating rooms, emergency departments, and by medics on the battlefield. Ketamine's use for the treatment of depression, anxiety, suicidal ideation, OCD, and PTSD is off-label and has not been approved by the FDA.

While Ketamine has not formally approved by the FDA for mental health treatments, many studies now exist that demonstrate it as an effective and rapid treatment option for certain mental health conditions. Benefits may occur after only one treatment, though typically an initial course of several treatments is required for a more robust response.

1. PROCEDURE – KETAMINE INFUSION THERAPY

An Intravenous line (IV) will be started in an extremity (hand, arm, or leg) so you can receive IV Ketamine. Your blood pressure, heart rate, and oxygen saturation will be monitored prior to, during, and after the infusion procedure by your Ketamine provider. You will be receiving a subanesthetic dose of Ketamine by slow and continuous infusion. The duration of the infusion generally varies between 40-60 minutes. Depending upon your response to the first infusion, your provider may increase the dose incrementally with your subsequent infusions to maximize your response. Your provider will also often adjust the infusion rate during each infusion, depending on how you are responding, to maximize the effectiveness of each infusion. Other medications may also be administered if necessary, such as anti-nausea medication, sedatives (including benzodiazepines) for agitation, blood pressure medication, etc.

2. RISKS & SIDE EFFECTS

The risk of Ketamine usually depends upon the dose and the infusion rate. The dose being used for this purpose is generally lower than anesthetic doses and will be infused over a longer duration of time. Side effects usually go away on their own. The risk of side effects is higher with higher doses.

Common side effects:

- Hallucinations
- Vivid dreams or nightmares
- Nausea or vomiting
- Increased saliva production
- Dizziness
- Blurred vision
- Increased heart rate and/or blood pressure during the infusion

- Out-of-body experience during the infusion
- Change in motor skills during infusion

These symptoms generally dissipate when the infusion is stopped. If the symptoms are severe, medications can be used to treat those symptoms.

Uncommon side effects:

- Rash
- Double vision
- Pain and redness in the injection site
- Increased pressure in the eyes
- Jerky arm movements resembling a seizure

Rare side effects:

- Allergic reaction
- Irregular or slow heart rate
- Arrhythmia
- Low blood pressure
- Cystitis of the bladder: inflammation, ulcers, and fibrosis
- 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 infusions can cause the patient to have flashbacks, hallucinations, feelings of unhappiness, restlessness, anxiety, insomnia, and/or disorientation.
- The uncommon risk of a dosing error or unknown drug interaction that may require medical intervention including intubation or hospitalization.
- Starting an IV may cause temporary discomfort from the needle stick, bruising, and/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.
- It is not guaranteed that Ketamine will help resolve depression, bipolar disorder, PTSD, anxiety, or other mental health condition.

3. BENEFITS

Ketamine, unlike conventional anti-depressants, has been associated with a rapid decrease in depression, bipolar, suicidal ideation, OCD, and PTSD symptoms. The initial series of infusions is used to prolong the longevity of its improvement. While the goal is to improve symptoms, results cannot be guaranteed and there is no way to predict how any individual will respond to Ketamine infusion therapy. These effects can be transient and will most likely require further infusions.

4. SAFETY PRECAUTIONS

- I will not eat:
 - o Fried foods, fatty foods, or meat 8 hours prior to my infusion
 - o Light meals* 6 hours prior to my infusion
 - o Clear liquids** 2 hours prior to my infusion

*Light meals typically consist of toast and clear liquids. Light meals do NOT include meals that include ANY fried or fatty foods or meat.

**Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee.

- I will NOT drive a car, operate hazardous equipment, or engage in hazardous activities for 24 hours after each treatment as my 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 will refrain from alcohol or other substances prior to, and for 24 hours after an infusion.
- I will tell the clinic about all medications I am taking, especially narcotic pain relievers and barbiturates.
- If I experience a troublesome side effect after I leave the clinic, I should contact the medical staff of Adam O'Neill & Associates, LLC. If I cannot reach the clinic, I should call my primary care doctor, my psychiatrist, call 911, or go to my local emergency room.
- SUICIDAL IDEATION:
Psychiatric illnesses carry the risk of suicidal ideation (i.e., thoughts of ending one's life). If you have any of these thoughts now, at any time during your ketamine infusions, or at any point in the future (which cannot immediately be addressed by visiting with a mental health professional), seek emergency care at your local emergency room or call 911.

5. POTENTIAL FOR KETAMINE ABUSE AND PHYSICAL DEPENDENCE

Ketamine is a controlled substance and is subject to Schedule III rules under the Controlled Substance Act of 1970. Medical evidence regarding the risk of abuse and dependence suggests that Ketamine's abuse potential is equivalent to that of phencyclidine and other hallucinogenic substances, which are low risk in terms of abuse. However, cravings have been reported by some individuals and documented cases exist of overuse of illicitly obtained and diverted Ketamine. In addition, Ketamine can effect mood (feelings), cognition (thinking), and perception (imagery) that may make some people want to use it repeatedly. Therefore, Ketamine should never be used except under the direct supervision of a licensed provider. Such potential for abuse or dependence of Ketamine is greater when it is used outside of the office, where no provider monitoring exists.

6. ALTERNATIVE PROCEDURES AND POSSIBILITIES

No other procedure is available to produce the specific effect Ketamine provides though other alternatives are available such as electroconvulsive shock therapy (ECT), transcranial magnetic stimulation (TMS), and medication treatments. Mental health disorders are optimally treated with a combination of medications and therapy.

7. PREGNANCY OR BREAST FEEDING:

Receiving Ketamine and/or drugs during pregnancy may be harmful to a developing fetus. If you are a woman who is or will be breastfeeding or if there is a chance you may be pregnant, please inform your Ketamine provider immediately. If you become pregnant while receiving infusions, you should notify your medical providers immediately as the effects of Ketamine on the unborn child are undetermined

YOU HAVE THE OPTION TO TAKE A PREGNANCY TEST IN OUR OFFICE PRIOR TO EACH INFUSION.

Should you decline to take a pregnancy test, by your signature below, you agree to waive, release, and discharge any and all liability, claims, damages, actions, or causes of action against Adam O'Neill & Associates, LLC and its employees, staff, and providers for any negative effects or complications to the unborn child as the result of

the administration of ketamine infusions.

8. IMPORTANT CAVEATS

Ketamine infusion therapy is not a comprehensive treatment for depression, anxiety, or any psychiatric conditions. These infusions 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.

9. CONFIDENTIALITY

Your privacy and all therapy records will be kept confidential. They will be maintained with the same precautions as ordinary medical records. The results of this ketamine therapy may be published in clinical literature. Published reports will not include your name or any other information that would identify you.

10. VOLUNTARY NATURE OF THE TREATMENT

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

11. 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 reasons.

12. MISSED OR LATE APPOINTMENTS

I understand that I will be charged the cost of an infusion for missed appointments or appointments not cancelled within 48 hours of the visit. The patient will still receive the total 6 infusions as established in the ketamine treatment protocol.

I understand that if I arrive more than 15 minutes after the original appointment time, I may not receive my infusion and will be charged the cost of an infusion. The appointment will be rescheduled for a later date.

13. PAYMENT

Adam O'Neill & Associates will bill the patient for the first 6 loading dose infusions on the day of their pre-infusion appointment. These 6 sessions are billed together. The total cost for these infusions is \$450 per infusion.

Future booster infusions will be billed the day of or the day before the scheduled treatment day. Booster infusions cost \$450 per infusion.

14. PATIENT CONSENT

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 my psychiatric symptoms.

Receiving ketamine infusions at Mosaic Infusions & Wellness does not establish a psychiatric provider-patient relationship. Our role in this setting is limited to the evaluation for and administration of ketamine treatments. We do not provide ongoing psychiatric care, medication management, or psychotherapy through the ketamine clinic alone. However, psychiatric medication management is available through our practice for patients who are separately established with our mental health services. Please let us know if this is something you are interested in. We encourage all patients to maintain care with their own mental health provider unless otherwise arranged.

I agree to allow Adam O'Neill & Associates, LLC, 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 understand and acknowledge that Ketamine is not an FDA-approved treatment for depression, bipolar disorder, suicidal ideation, PTSD, or OCD.

I understand and acknowledge that my taking part in this procedure is my choice.

I understand and acknowledge that I may decide not to take part in or to withdraw from the procedure at any time. I know that I can withdraw from this procedure without penalty or loss of treatment.

I understand and acknowledge that my provider may stop the infusion without my consent.

I understand and acknowledge that Ketamine infusion therapy may not help my depression, bipolar disorder, suicidal ideation, PTSD, or OCD.

I give my consent to the use of sedation, antinausea, blood pressure, and other medications necessary for agitation, nausea, blood pressure control and other complications of the infusion.

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

I acknowledge that 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.

Patient Name

Patient Signature

Date

Provider Name

Provider Signature

Date