

NW Ketamine Infusion

Informed Consent for Ketamine Infusion Therapy

What is ketamine and what is off-label use?

Ketamine is a drug approved by the FDA for use in children and adults as an anesthetic agent. FDA approval does not imply that there are no risks associated with the drug but that the benefits outweigh any potential risks when used as directed. When administered in a subanesthetic or low-dose infusion, there is strong evidence to suggest that ketamine may provide relief of symptoms of depression, anxiety, post-traumatic stress disorder (PTSD), acute and chronic pain as well as other mood disorders. Ketamine's use for these indications is considered off-label because these aren't the original indications that ketamine received approval for. However, once a drug has been approved by the FDA for one purpose, healthcare providers may prescribe the drug for other purposes that they judge to be medically appropriate. Off-label use of medications is ethical, legal, and common. In fact, about 20% of all prescriptions written in the US today are considered off-label.

Why is ketamine being recommended?

Numerous studies show that ketamine may be beneficial in the treatment of depression, anxiety, PTSD, acute and chronic pain as well as other mood disorders. When administered by IV infusion, ketamine may help improve symptoms rather quickly. Improvements may last several days up to a few months. A series of infusions is recommended so that symptom relief has a longer duration of action. While the goal is improvement of symptoms, individual results cannot be guaranteed, and it is possible that you will not benefit from the treatment.

What will be done?

You will be receiving ketamine by IV Infusion. This means an IV catheter will be inserted into a vein in your hand or arm and ketamine will be slowly infused. During the infusion your level of sedation, blood pressure, heart rate and rhythm, oxygen concentration, and respirations will be monitored. An anesthesia provider will be always readily available to intervene if necessary. After the treatment, you will remain in the clinic for an additional recovery period. For mood disorders, current research recommends that you receive six treatments over a two-week period, but the exact timing is not crucial. Additional maintenance treatments may be appropriate and occur about once a month or less frequently as desired. For pain conditions, the frequency of ketamine infusions is based on your specific type of pain and response to therapy.

Required safety precautions:

- You may not eat **4 hours** before the infusion. You may drink water, apple juice (with no pulp) or clear broth, up to **2 hours** before the infusions. Please note that coffee with cream or milk is considered a meal. You may drink **black** coffee for up to **2 hours** before. No gum, mints, or anything else by mouth for 2 hours prior to the infusion.
- You may NOT drive a car, operate hazardous equipment, or engage in hazardous activities for the remainder of the day as reflexes may be impaired. Another adult will need to drive you home and must be present prior to your discharge.
- You should refrain from alcohol and any other unprescribed drugs for **24 hours** prior-to and following ketamine administration. The use of other drugs may decrease the effectiveness of the ketamine treatments and is generally discouraged throughout the entire course of treatment.

- You must disclose all medications you are taking, especially narcotic pain relievers, benzodiazepines, barbiturates and muscle relaxers.

What are the possible risks?

Every procedure has possible risks or side effects. Side effects of receiving a subanesthetic dose of ketamine are rare but not impossible and generally resolve rapidly when the infusion is concluded. These may include but are not limited to:

- Change in heart rate, blood pressure or respiration
- Nausea or vomiting
- Blurred Vision
- Confusion, irritation, or excitement
- Floating sensation ("out-of-body ")
- Euphoria
- Hallucinations
- Twitching of the muscles or change in motor skills
- Bladder inflammation or urinary frequency
- Increase in intraocular pressure
- Allergic reaction

Side effects of receiving an IV are:

- Discomfort at the site of placement
- Bruising
- Infiltration
- Infection

Important Notices and Agreements:

Ketamine is not a first-line or stand-alone treatment for mood disorders or chronic pain and is intended to be one component of a multimodal treatment regimen.

While receiving ketamine infusions, you agree to remain under the care of a qualified primary care or mental health provider and have your overall health care directed by him or her. It is strongly recommended that you engage in therapy sessions with a qualified professional while receiving ketamine treatment. Research has shown that the combination of ketamine treatments with psychotherapy is beneficial. NW Ketamine Infusion and its employees will not advise or direct your medical care beyond the safe administration of the ketamine infusions.

Psychiatric illnesses carry the risk of suicidal ideation (thoughts of ending one's life) or thoughts of harming others. If you experience thoughts of harming yourself or others call 911 immediately.

Patient Consent for Ketamine Treatment:

My request for ketamine infusion treatments as described is entirely voluntary. I have read this consent form in its entirety and understand the information provided. The alternatives, risks, benefits, and side effects have been discussed and all of my questions have been answered. I understand that I may refuse ketamine treatments at any time and the treatments may be discontinued at the discretion of NW Ketamine Infusion or my referring provider.