



ALL ABOUT KETAMINE EDUCATION DOCUMENT

INFORMED CONSENT FOR IN-OFFICE KETAMINE INFUSION THERAPY

Ketamine is a dissociative class medication that is considered a schedule III-controlled substance. It is predominately used in the emergency department and in the operating room as an anesthetic medication. Ketamine is FDA approved for anesthesia and for pain relief during procedures. Ketamine is not considered FDA approved to treat depression, PTSD, acute or chronic pain, or any additional conditions outside of anesthesia and pain relief during procedures.

The use of ketamine to treat the above conditions is considered “off label” by the FDA. There is nothing wrong with using medication for “off label” purposes as a large percentage of medication prescribed in this country is for “off label” use. Ketamine infusion therapy for psychiatric conditions and acute or chronic pain is considered safe, even though it is considered “off label”, but be aware that Ketamine has been used safely over the past 50 years. Ketamine has been shown to improve the symptoms of various psychiatric conditions and pain in certain populations. Everyone’s response to treatment will be different but individuals usually report improvements in psychiatric symptoms and pain but be aware that symptom relief cannot be guaranteed. You need to be aware that symptom relief can last from days to months, therefore multiple treatments might be recommended or required for long term symptom relief.

There are no long-term studies to show the safety or effectiveness of repeated ketamine treatments, therefore the potential long-term risks or treatment efficacy cannot be established for the treatment of chronic pain disorders, depression, PTSD, anxiety, and other psychiatric conditions.

What Can I Expect with Treatment?

The procedure for ketamine infusion is straight forward. You will receive treatment by intramuscular (IM) injection in your both of your upper arms or right and left thighs. You may also receive an intravenous (IV) line started into a vein of your hand or arm, an intramuscular (IM) injection in your upper arm, right and left thighs, and/or a subcutaneous (subq) injection in your hand or arm.

You will have your vital signs monitored frequently during treatment to include but is not limited to your heart rate, blood pressure, and oxygen saturation under the supervision of a licensed medical provider and/or registered nurse.



After the treatment, you will have a recovery period of 30 minutes to 2 hours depending on your response. You can expect at minimum to have up to 6 treatments over the course of 3 to 6 weeks for a complete loading series. Maintenance treatments are preferred. You may have 2 treatments the next month and only 1 treatment the month after. A total of 9 treatments in 3 to 5 months is preferred but may not be necessary depending on your progression. Some clients can go longer without treatment however this dependent on the client. Plan for at least a quarterly visit.

Risks

Any procedure or medication carries with it possible risks and side effects. Even though significant side effects are rare, you need to be aware of all the possible risks and side effects before starting treatment. Unknown or unexpected side effects or risks could also occur.

Most side effects are mild in nature. Possible side effects include but are not limited to:

- Elevations in blood pressure and heart rate.
- Laryngospasm
- Urinary frequency, urgency, hesitancy, or burning with urination.
- Dizziness
- Headache
- Increased saliva production
- Restlessness
- Impaired coordination
- "Out of body" experiences
- Twitching of arms and legs
- Decreased appetite
- Nausea and vomiting
- Pain, rash, bruising, or possible infection at the IV site

More rare and serious side effects include but are not limited to:

- Blurred or double vision
- Hives and allergic reaction
- Increased ocular (eye) pressure
- Hallucinations and flashbacks
- Increased mania or hypomania in bipolar disorder
- Increased suicidal thoughts and ideation
- Cystitis
- Slowing of heart rate
- Irregular heart rhythm
- Low blood pressure

Ketamine also carries with it a risk of abuse and tolerance, especially if you have a history of drug abuse or dependence. This is rare though as ketamine does not have a physiological withdrawal syndrome associated with it and most patients do not develop cravings for ketamine.



As with the administration of any type of medication, especially an anesthetic, there is a risk of dosing errors, drug interactions, and rare serious side effects that could require intubation, anaphylactic treatment, and/or hospitalization. These can be serious and life threatening. For this reason, it is imperative to be truthful with your medical history and all medications, supplements, or illicit drugs you are taking.

Female Only: You should not receive ketamine if you are pregnant, breastfeeding, could be pregnant, or trying to get pregnant as ketamine could harm the developing fetus. If you believe you could possibly be pregnant, then a pregnancy test will be available for you before treatment. Please notify a staff member.

Benefits

Ketamine therapy for depression, PTSD, and anxiety has been associated with decreases in the symptoms associated with such psychiatric conditions. Every patient's response to treatment is different. The length of time of symptom relief can vary from person to person as can the intensity of relief. Your individual response to therapy will be monitored by your treating provider and additional treatments could be recommended depending on your response.

Preparation for Treatment and Risk Management

- You must abstain from the use of alcohol, cannabis, and other illicit substances for a period 24 hours before treatment and 24 hours after treatment.
- You should not make any life changing or legal decisions for up to 12 hours after the infusion.
- You may not eat for at least 4 hours prior to treatment.
- You may have clear fluids up to 2 hours prior to treatment.
- You may not operate heavy machinery or drive motor vehicles for 24 hours after the ketamine treatment.
- You can take your regular medications as normal on the day of treatment. If you are taking any of the following medications, you must hold them the day of your treatment:
 - Stimulants that can increase your blood pressure and heart rate
 - Benzodiazepines such as Xanax, Klonopin or Ativan.
 - Lamictal (Lamotrigine)
 - MAOIs
- You must also notify your medical provider who is overseeing your mental health and/or pain conditions that you are seeking treatment with ketamine. It is important that you maintain seeing your mental health provider and the provider managing your pain for ongoing therapy and treatment outside of ketamine therapy.



WHAT TO EXPECT WITH KETAMINE TREATMENT

Tips for more positive results from your Ketamine Infusions

Dress comfortably so that you may relax during your infusion; even kicking off your shoes may make you more comfortable.

Optimizing your state-of-mind prior-to & during an infusion is vital. Many things can have either a positive or negative effect on your session.

- 1) Blocking outside noise is helpful; we have noise-canceling headphones or earplugs for you to use
- 2) Many people find music very helpful; we have a playlist of meditative music without words that we can play for you. You may use your own phone with your own playlist, but an incoming text or call can be extremely disruptive to your session
- 3) Many patients prefer to keep their eyes closed during their infusion, but we also have eye masks for you to use if you like.

The day before an infusion & the day of an infusion, avoid situations that will bring you stress, anxiety, or anger, such as a difficult family member or neighbor. Also avoid sad or scary movies/shows the day before an infusion. Again, what goes into your brain prior-to & during an infusion can impact whether your session is positive or negative.

- Whomever is driving you to & from your session should understand that being supportive & positive is the most helpful thing they can do for you.
- If your phone is nearby during infusions, please remember to mute it or turn it off.
- Bring sunglasses to wear when you leave; you may be more light sensitive after your infusion.
- You are welcome to bring a blanket or pillow; we also have those things here for you to use.
- Hydrate well the day before & choose nutrition that is healthy; avoid alcohol, marijuana, & benzodiazepines the day of your infusion.

Practice meditating; choose several positive & happy mantras. If your ketamine infusion begins to cause anxiety, these practices can help you redirect your thoughts away from the anxious thoughts or dreams.

Please communicate with us during your treatment if you begin to feel anxious or tense. We can help you talk through your feelings & redirect your thoughts.



Other things to keep in mind about ketamine infusions

Ketamine is not a cure.....it will not cure your chronic pain, it will not cure your depression, it will not heal your underlying traumas, it will not cure any other illnesses. It is a tool to help, just like other medications & treatments. But like other treatments, you will need to keep utilizing it to continue receiving the benefits that it brings you.

It is a myth that ketamine will make a depressed person happy. In reality, ketamine treatments will make you feel more resilient. The stressors don't change... what changes is your ability to cope & your willingness to engage in other treatments, both for mental health & physical health.

One infusion will not do much, even if you feel a positive result. Ketamine needs to build up in your system in order for the effects to be longer-lasting. It needs time to reset the NMDA receptors & help your synapses heal. Don't give up early... trust the process.

What dose is best for my "XYZ" diagnosis? Because every person is different, it is difficult to know what your best dose will be. But there are guidelines for starting points & we can go up or down from there, based on your feedback. So being honest with your provider is important. A good clinic & provider will be willing to adjust up or down as needed.

Whether you're getting ketamine for chronic pain or mood disorders (or both), it's very common that you'll still have good days & bad days. **Some people even get a little worse after an treatment before they begin to feel better overall; it's called a treatment flare.** Utilize all of the tools that you know to manage your times of down-swing. And know that it will get better!

Do some people develop a tolerance to ketamine? Yes, it is possible. Just like with many medications, there doesn't seem to be a way to prevent it. Communicate with us if your treatments aren't helping as they used to. NeuropsychiatryTX has a protocol where we can increase your dose by 10% if your dose seems to start to lose its effectiveness. From what we've observed & heard from other providers, this may happen to long-term ketamine users about once a year. That's why it can be important to start at the lowest dose that's effective for you.



I've heard that some people are able to come off of their antidepressants... is that true? In some cases, with the supervision of their mental health provider, some people have been able to reduce or eliminate their antidepressants, mood stabilizers, &/or anti-anxiety medicines. However, most people do continue to utilize antidepressants in combination with ketamine; they find that the ketamine seems to cause the anti-depressants to work more effectively.

If you develop pain that feels like it's in the location of your bladder, it's possible that the ketamine is causing this pain. It's rare with lower doses for mood disorders, but with higher doses for pain, the ketamine being metabolized by your body can irritate your bladder. Let us know... we have a list of OTC medications that can help. Also, if you've been diagnosed with Interstitial Cystitis, it's important that we know... we will have you take those same OTC medications from the start.

Remember to visit the bathroom before each treatment!

Wherever you receive your ketamine treatments, that clinic should be willing to share with you what dose you are receiving, over how much time, & what other medications you will receive along with the ketamine. You should always be told what you are being given; if any place doesn't want to tell you, consider avoiding them.

We enroll you in Mood Monitor, an app that helps you track how you're feeling. You can also try keeping a journal of your daily mood as a way to track your progress. This is especially helpful if your changes happen more slowly. However, if you have OCD, keeping a journal may not be a good idea as it may cause you to obsess over it. Your entries don't need to be very long, just meaningful to you. Maybe even give your mood a number... something that you can use to quantify your current status. When you read back over several days or a week of entries, you'll be surprised at your progress!

And finally, if you don't think ketamine will work, then it won't work. You must tell yourself that the ketamine is making changes in your body, it's healing your synapses that have become damaged through stress over time. Sometimes the changes are subtle & you may not pick up on those small clues that things are improving.

The improvements have been described by some as "sliding a dimmer switch" rather than "flipping a switch"... things may brighten slowly!

Part of the process is knowing that the ketamine truly is healing your body; the other part of the process is becoming aware of those subtle changes. You will not go from 0-60 overnight, & if you're convinced that it isn't working, then it won't, & you'll be back too square one with yourself. As you are trusting the process, do small things that bring you pleasure.



Comments from ketamine patients about their experiences:

“Going for my first infusion, I was so nervous I could barely speak at the beginning. I made small talk while waiting for the ketamine to kick in....it helped take my mind off of the anxiety. But the infusion went great & was ten times easier than I expected.”

“Ketamine has helped in ways I didn’t necessarily expect. It reduced my focus & concern on my issues.”

“The dissociation is dreamlike – if managed well, the visions can be beautiful & even breathtaking. I’ve said “wow” on more than one occasion. If the visions turn negative, let your provider know.”

“Ketamine is like a SciFi movie where the character is in another dimension.”

“A ketamine infusion is like being on a 3-D ride at Disney World!”

“ I’m very social & I tried to chat. But when I let my mind go & fully relax, when I meditate & visualize my issues leaving my body, I realize that the positive effects of the infusions last longer. I knew it sounds totally goonie & I wouldn’t have believed such things would work, ever!”

“I really wasn’t aware of how my pain was improving until I realized one day that tying my shoes was much easier than it normally was! As I looked back, I realized that I had been slowly improving over the past week & it made me laugh out loud when I realized the progress I had achieved.”

“I think the lights & vivid colors that we see during an infusion is the light within our soul. While it sometimes dims in our reality, ketamine recharges it. Brightens it, brightens us.”



KETAMINE BEFORE & AFTER VISIT INSTRUCTIONS

To have SAFE and EFFECTIVE treatment, it is important that you adhere to the following before and after visit instructions.

Before your appointment:

- Plan to be at the clinic at least 20 minutes before your infusion/injection
- Arrange to have someone available to drive you home after the infusion/injection
- Plan to be in the clinic for an additional 1-2 hours after the infusion/injection for monitoring & recovery. For example, if you are going to have a 40-minute infusion/injection, be prepared to be here for about 2 hours.
- Avoid eating any solid food 4 hours prior to treatment. You may have clear liquids up to 2 hours prior to your treatment.
- You must abstain from the use of alcohol, cannabis, and other illicit substances for a period 24 hours before treatment and 24 hours after treatment.
- Do not take any opioid pain medication for at least 6 hours prior to your infusion/injection.
- You can take your regular medications as normal on the day of treatment. If you are taking any of the following medications, you must hold them the day of your treatment:
 - Stimulants that can increase your blood pressure and heart rate
 - Benzodiazepines such as Xanax, Klonopin or Ativan.
 - Lamictal (Lamotrigine)
 - MAOIs

After your appointment:

- You may not operate heavy machinery or drive motor vehicles for 24 hours after the ketamine treatment. Ensure you have someone to drive you home that you trust.
- You should not make any life changing or legal decisions for up to 12 hours after the infusion/injection.
- A light meal is recommended after the infusion/injection.
- Do not take benzodiazepines or opioid pain medication for at least 4 hours after your infusion/injection.
- Monitor your IV, IM or Subcutaneous site for redness, pain, warmth, or swelling. This could be a sign of infection or an adverse reaction.
- Continue routine follow up with your mental health and/or primary care provider for continued treatment.
- If any mild side effects occur such as increased anxiety, hives, nausea, restlessness, or any additional non-life-threatening symptoms, please call NeuropsychiatryTX at 888-468-9669 immediately. If it is after hours or your call happens to get missed, then please report to your closest urgent care or emergency department.



NTX

Neuropsychiatric Treatment Center

1755 Coburg Rd. Suite 502

Eugene OR 97401

Phone: 888-468-9669

Fax: 541-632-4858

Email: admin@neuropsychiatrytx.com

- If any type of adverse events occurs such as suicidal ideation, psychosis, shortness of breath, trouble swallowing, chest pain, severe headache, changes in consciousness, or anything else that is concerning, call 911 or report to the emergency department immediately.