

Ketamine Infusion Clinic Informed Consent

Since the early 1960s, the Food and Drug Administration (FDA) has required drugs used in the United States be both safe and effective. The label information on the container, in the package insert, in the Physician's Desk Reference (PDR) and in any advertising can indicate a drug's use only in certain "approved" doses and routes of administration for a particular condition. The use of a drug for a disease not listed on the label, or in a dose, or by a route not listed on the label is considered to be an "off-label" use of the drug. Physicians, based on their knowledge and on available current information, may use a drug for a use not indicated in the "approved" labeling if it seems reasonable or appropriate.

Ketamine has not been approved by the FDA to treat depression, bipolar disorder, PTSD, or chronic pain.

- I know that ketamine is NOT an FDA approved treatment for pain, 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 chronic pain, depression, bipolar, or PTSD.
- I have had a chance to ask the doctor questions about this treatment.
- They have answered those questions to my satisfaction.
- The nature and possible risks of a ketamine infusion have been fully explained to me.
- 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.

An intravenous line (IV) will be started in an extremity so you can receive ketamine. The risk of venipuncture (IV line insertion) may include temporary discomfort from the needle stick, bruising, infiltration or infection. Fainting may also occur. Your blood pressure, heart rate, and oxygen saturation will all be monitored throughout the infusion under the supervision of a physician.

Risks / Side Effects:

Side effects normally depend on the dose and how quickly the injection is given. The dose being used is lower than anesthetic doses and will be given slowly over 40-60 minutes. These side effects often go away on their own.

Common side effects:

- hallucinations
- nausea and vomiting
- increased saliva production
- dizziness
- blurred vision
- increased heart rate and blood pressure during the infusion -out of body experience during the infusion
- change in motor skills
- These symptoms dissipate when the infusion is stopped. If they are severe, another medication such as a sedative can be used to treat the symptoms. You should not drive the day of an infusion and can resume driving the following day.

Uncommon side effects:

- rash
- double vision
- pain and redness in the injection site
- increased pressure in the eye
- jerky arm movements resembling a seizure
- allergic reaction
- irregular or slow heart rate
- arrhythmia (abnormal heart rhythms)
- low blood pressure
- cystitis of the bladder: inflammation, ulcers, and fibrosis
- constipation
- elevated liver enzymes with multiple doses

Other Risks:

- Ketamine may cause various symptoms including but not limited to flashbacks, hallucinations, feelings of unhappiness, restlessness, anxiety, insomnia and disorientation.
- Allergic reaction from materials containing latex, Ketamine, and/or other medications or medical supplies
- Infection on skin, tissue, bones, joints, nerves, ligaments, possibly blood stream (Sepsis) and brain and may require hospitalization from medical supplies (IV catheter, IV tubing) and/or medications.
- Nausea, Vomiting and gastric contents (vomitus material) can be aspirated and can cause serious lung disease such as Aspiration Pneumonia or Aspiration Pneumonitis
- Changes in blood pressure, eye injury, peripheral nerve injury, drug reactions, cardiac arrest, strokes, heart attack, brain damage, paralysis or death

- There is a potential risk of dosing error or unknown drug interaction that may require medical intervention including intubation (putting in a breathing tube), or hospitalization.
- The risk of venipuncture may include temporary discomfort from the needle stick, bruising, infiltration or infection. Fainting may also occur.
- Risk of discomfort in answering questionnaires about your mental health and drug and alcohol use.
- Risk of other medications interacting with ketamine. It is very important that you disclose all medications, both prescription and over the counter, that you are taking.
- Ketamine may not help your pain, depression, bipolar disorder, or PTSD

Benefits

- Ketamine has been associated with a decrease in pain, depression, bipolar, and PTSD symptoms with results lasting for days to weeks to months. There is no way to predict how any single person will respond to ketamine infusion therapy. These effects may not be long lasting and will most likely require further infusions.

Risk Management

- You must report any unusual symptoms or side effects at once to the medical staff or the physician
- On the day of the infusion, you should NOT engage in any of the following after the infusion:
 - driving
 - drinking alcohol or using drugs
 - conducting business
 - participating in activities which require you to rely on motor skills or memory

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.

Withdrawal of Treatment

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



You have a pain problem and/or mood disorder that has not been relieved by routine treatments. Ketamine infusion therapy is now indicated for further evaluation or treatment of your pain and/or mood disorder. There is **NO** guarantee that Ketamine infusion therapy will cure your pain and/or mood disorder, and in rare cases, it could become **WORSE**, even when the infusion was completed in a technically perfect manner. The degree and duration of relief varies from person to person, so after the infusion therapy, we will reevaluate your progress, then determine if further treatment is necessary. Your physician will explain the details of the procedure listed below. Alternatives to the procedure include medications, physical therapy, psychotherapy, counseling, acupuncture, surgery, interventional treatments, etc. Benefits include increased likelihood of correct diagnosis and /or of decrease or elimination of pain or mood disorder.

The incidence of serious complications listed above requiring treatment is low, but it may still occur. Your physician believes the benefits of Ketamine Infusion Therapy outweigh its risks or it would not have been offered to you, and it is your decision and right to accept or decline to have the procedure done. I have read or had read to me the above information including the Pre-Procedure Patient Instruction page. I **UNDERSTAND** there are risks involved with the Ketamine infusion, to include rare complications, which may not have been specifically mentioned above. The risks have been explained to my satisfaction and I accept them and consent to the Ketamine Infusion Therapy. The options, risk and benefits of the Ketamine Infusion Therapy have been discussed with me. All my questions have been answered to my full satisfaction. By signing this request form, I am indicating that I understand the contents of this document, agree to its provisions and consent to the administration of Ketamine. I am also acknowledging that the practice of anesthesiology, medicine and pain management is not an exact science and that no one has given me any promises or guarantees about the administration of Ketamine or its results. All blanks or statements requiring insertion or completion were filled in before I signed this consent and all of my questions have been answered to my satisfaction. I have been advised not to operate machinery, drive a car, and/or make important decisions for at least 24 hours after the infusion therapy.

Patient's Name: _____ Date: _____

Physician's Name: _____ Date: _____

Witness: _____ Date: _____