

INFORMED CONSENT FOR KETAMINE INFUSION

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.

IV Ketamine has not been approved by the FDA to treat depression, bipolar disorder, anxiety, migraines, fibromyalgia, OCD, nor PTSD.

1. PROCEDURE – KETAMINE INFUSION THERAPY

An intravenous line (IV) will be started in an extremity so you can receive ketamine. Your blood pressure, heart rate, and oxygen saturation will all be monitored throughout the infusion under the supervision of a physician.

2. RISKS/SIDE EFFECTS

Risk of ketamine: 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, greater than 1% and less than 10%:

- 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, greater than 0.1% and less than 1%:

- rash
- double vision
- pain and redness in the injection site
- Increased pressure in the eye
- jerky arm movements resembling a seizure

Rare side effects, greater than 0.01% and less than 0.1%:

- allergic reaction
- irregular or slow heart rate
- arrhythmia
- low blood pressure
- cystitis of the bladder: inflammation, ulcers, and fibrosis

Other Risks:

- Ketamine can cause various symptoms including but not limited to flashbacks, hallucinations, feelings of unhappiness, restlessness, anxiety, insomnia and disorientation.
- 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, 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 depression, bipolar disorder, migraines, fibromyalgia, chronic pain, or PTSD

3. Benefits

Ketamine has been associated with a decrease in 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.

4. Risk Management

You must report any unusual symptoms or side effects at once to the medical staff.

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

5. 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.

6. 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.

7. PATIENT CONSENT

- I know that ketamine is not an FDA approved treatment for depression, bipolar disorder, anxiety, migraines, fibromyalgia, OCD, nor 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 depression, bipolar, migraines, fibromyalgia, chronic pain, 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.