

MGM KETAMINE INFUSION CENTER

KETAMINE THERAPY INFORMED CONSENT

This consent form contains information about the use of subanesthetic ketamine therapy for the treatment of depression and other psychiatric illnesses. Ketamine has been approved by the Food and Drug Administration (FDA) for use as an anesthetic agent for many years. The use of ketamine in lower, subanesthetic doses to treat depression is a newer, off-label use of ketamine. It is usually used after other treatments have been unsuccessful. While ketamine is not formally approved by the FDA for this use, there are now many studies that demonstrate it may be an effective and rapid treatment option for multiple disorders including major depressive disorder, bipolar disorder, and substance use disorder. Benefits may occur after only one treatment, though typically an initial course of several treatments are required for a more robust response. If your depressive symptoms respond to this initial course of ketamine therapy, you may receive further treatments. It is recommended that you continue treatment with other medications and ongoing psychotherapy as ketamine therapy works best when part of an integrated treatment program.

OVERVIEW OF SUBANESTHETIC KETAMINE TREATMENT

Ketamine can be given as an intravenous (IV) injection or drip, intramuscular (IM) injection, or nasal spray. For IV treatment, an intravenous catheter is placed, and ketamine is infused over the following 40 minutes at a total dose of 0.5 mg/kg body weight. You will remain awake and able to talk during the procedure, but your perception and mental state will likely be altered by the ketamine. You will return to a normal mental state as the immediate medication effects wear off.

You may ask your provider any questions you may have concerning the procedure or effects of ketamine at any time. Your consent to receive Ketamine may be withdrawn by you and you may discontinue your participation at any time up until the actual dose has been administered.

CONTRAINDICATIONS TO KETAMINE THERAPY

Ketamine therapy should not be used in patients with the following:

- Active substance abuse
- Psychosis
- Active suicidal ideation/ plans
- History of increased intracranial pressure
- Pregnancy or breastfeeding mother
- Uncontrolled high blood pressure
- Untreated hyperthyroidism
- Prior hypersensitivity or negative reaction to ketamine

POSSIBLE SIDE EFFECTS OCCURING DURING KETAMINE THERAPY

These side effects are transient and subside as the immediate effects of the medication wear off.

- Impaired balance and coordination
- Sleepiness
- Headaches
- Nausea or vomiting, loss of appetite
- Blurred or double vision
- Slurred speech
- Confusion, excitability, anxiety
- Impaired ability to see, hear or feel things accurately
- Sense of time may be altered
- Elevation of pulse or blood pressure
- Nystagmus (rapid eye movements), rare
- Elevation of intraocular pressure (increased pressure in the eyes), rare
- Allergic reactions, rare

-The altered state of consciousness produced by ketamine usually lasts approximately 30 minutes after an IV infusion but can last longer. The impaired sense of balance, dizziness, and possible nausea gradually subsides over three to six hours. Patients cannot drive themselves home after ketamine treatment.

-Because of the risk of nausea and vomiting, please refrain from eating and drinking for at least the 4 hours preceding the session. If you are unduly nauseated during treatment, you may be offered an anti-nausea medication.

-Ketamine can cause a significant increase in blood pressure or heart rate (pulse). If monitoring shows this has occurred, you may be offered medication to lower your blood pressure or heart rate.

-Agitation may occur during the course of a ketamine session. If you are uncomfortable, you may be offered medication to help you relax.

-Chronic, high dose, recreational abuse of ketamine, can cause urinary tract symptoms and even permanent bladder dysfunction, though no significant effects have been reported with medical use.

Risks of having an IV placed:

- Mild discomfort at site of placement
- Fainting
- Bruising
- Bleeding
- infection

REGARDING POTENTIAL FOR KETAMINE ABUSE AND PHYSICAL DEPENDENCE

Ketamine belongs to a group of chemicals classified as hallucinogens (“psychedelics”). Ketamine is a controlled substance and is subject to Schedule III rules under the Controlled Substance Act of 1970. There is no evidence that medically prescribed ketamine therapy, administered as single or repeated doses, has increased the risk for substance use disorders. Medical evidence regarding the issue of drug abuse and dependence suggests that ketamine’s abuse potential is low risk in terms of abuse liability when medically prescribed, with potential for

low to moderate physical dependence when recreationally abused. Ketamine should never be used except under the direct supervision of a licensed physician.

NOTE ON SUICIDAL IDEATION

Psychiatric illnesses carry the risk of suicidal ideation (thoughts of ending one's life). Any such thoughts you may have now, at any time during the weeks of your ketamine infusions, or at any point in the future, which cannot be immediately addressed by visiting with a mental health professional, should prompt you to seek emergency care or to call 911.

INFORMED CONSENT

By signing this form I agree that:

1. I understand that I am to have no food or drink 4 hours prior to my ketamine session.
2. I fully understand that ketamine sessions can result in a transient, but profound change in mental state and may result in unusual psychological and physiological effects. I will be discharged from the office when I am sufficiently recovered from the infusion state.
3. I understand that I need to have someone drive me home from the sessions, and not engage in any driving or hazardous activity without at least one night's sleep after treatment.
4. I give my consent to the use of additional medications if deemed necessary to treat for agitation or high blood pressure or high pulse rate.
5. I have fully read this informed consent form describing subanesthetic ketamine therapy. I have had the opportunity to raise questions and have received satisfactory answers. I understand the risks and benefits, and I freely give my consent to participate. I have been given a signed copy of this informed consent form, which is mine to keep.

PATIENT SIGNATURE _____ DATE _____

PRINTED NAME _____

PHYSICIAN STATEMENT

I have carefully explained the nature of subanesthetic ketamine therapy to this patient. I hereby certify that to the best of my knowledge, the individual signing this consent form understands the nature, conditions, risks, and potential benefits involved in participating in ketamine therapy.

PHYSICIAN SIGNATURE _____ DATE _____