

Informed Consent for Ketamine Infusion

Patient Name: _____

Before you decide to take part in this procedure, it is important for you to know why it is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

Please closely read the information below closely and ask one of the clinical staff if there is anything that is not clear or if you would like more information. If you do decide to take part, your signature on this consent form will show that you received all of the information below, that you were able to discuss any questions and concerns you had with a member of the staff, and that you consent to treatment by Vitalitas Denver PC, including any and all repeated Ketamine infusions.

Ketamine is widely used in emergency departments and operating rooms for the purposes of surgical sedation. **Ketamine has not been approved by the Food and Drug Administration (FDA) to treat depression or other psychiatric illnesses or pain conditions. This is not a research study but is rather a clinical procedure. This procedure is not being monitored by the Institutional Review Board (IRB) or FDA.**

A. Procedures

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.

Under the supervision of a physician, you will receive ketamine through a vein in your arm. The dose you receive will be determined by the physician based on your circumstances. For the treatment of depression, patients most commonly receive between 0.5 mg to 1.0 mg of Ketamine per kilogram over approximately 40 minutes, followed by a 20 to 30 minute recovery time. For the treatment of chronic pain, patients most commonly receive between 50 to 100 mg of Ketamine per hour over two to four hours, followed by a 1 to 2 hour recovery time.

You will be monitored and then released to return home. **You must arrange for transportation home from your appointment. You cannot drive home after the procedure and should not make important decisions or operate machinery for the rest of the day.**

B. Risks of Ketamine Infusion

Off-Label Use

Before a drug can be approved, a company must submit clinical data and other information to the Food and Drug Administration ("FDA") for review. The company must show that the drug is safe and effective for its intended uses. "Safe" does not mean that the drug has no side effects. Instead, it means the FDA has determined the benefits of using the drug for a particular use outweigh the potential risks. Once

a drug has been approved by the FDA for one purpose, healthcare providers may generally prescribe that drug for other purposes when they judge that it is medically appropriate for their patient. The practice of prescribing a drug for a purpose other than that for which it is approved is known as "off-label" use.

Ketamine has not been approved by the FDA to treat depression or other mental health disorders or pain conditions. IV Ketamine Infusion for the treatment of depression or other mental health disorders or pain conditions is an off-label use of this drug. Ketamine is a promising treatment for people with treatment-resistant depression, other psychiatric disorders and complex chronic pain conditions. However, there is limited long-term safety and effectiveness data available for these diagnoses. Accordingly, there are potential and currently unknown risks to the administration of Ketamine in repeated doses, and there is insufficient evidence of the safety of Ketamine in repeated doses.

Any procedure has possible risks and discomforts. The procedure may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unforeseeable risks may also occur. **It is important that you are truthful and forthcoming with Vitalitas Denver about your medical history and past and present drug usage as it may affect your response to IV Ketamine treatment.**

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 are usually mild and often dissipate within hours after the infusion is stopped.

Uncommon side effects

Rash, double vision, pain and redness in the injection site, headache, insomnia, delirium

Rare side effects

Allergic reaction, irregular or slow heart rate, arrhythmia, low blood pressure, cystitis of the bladder (bladder inflammation, ulcers, and fibrosis), memory loss, elevated liver enzymes or liver damage.

Other Risks:

Ketamine can cause various symptoms including but not limited to flashbacks, hallucinations, feelings of unhappiness, restlessness, anxiety, insomnia and disorientation. Individuals with a history of drug misuse or dependence can develop a dependency on ketamine. The amount of ketamine used in treatment of depression is much lower than the amount used for surgery sedation, but there is limited information about long-term safety and effectiveness and risk for addiction with repeated doses of ketamine.

With administration of any medication, including IV Ketamine, there is a risk of dosing error or unknown drug interactions which may require medical intervention

including but not limited to intubation (placement of a breathing tube) and/or hospitalization. These risks can be serious and possibly fatal. **To reduce these risks, it is very important that you disclose all medications, supplements, and/or other drugs that you are taking.**

To administer the Ketamine, an IV will need to be inserted into your extremity. The risk of venipuncture may include temporary discomfort from the needle stick, bruising, bleeding, nerve damage, pain, infection and fainting.

Ketamine may not alleviate your symptoms. Ketamine may only temporarily relieve symptoms and may require additional future infusions.

Pregnancy

Receiving Ketamine or other drugs during pregnancy may be harmful to a developing fetus. It is the policy of Vitalitas Denver that women who are pregnant or breastfeeding or women who may be pregnant should not undergo IV Ketamine Infusion. If you are pregnant or breastfeeding, or if there is any chance that you may be pregnant, you should inform clinical staff immediately, before treatment. Vitalitas Denver offers women the option to undergo a pregnancy test in our office prior to your infusion.

C. Benefits

For Chronic Pain:

Ketamine has been associated with a decrease in chronic pain symptoms with patients reporting varying lengths and levels of pain-relief. It is difficult to predict how any single person will respond to ketamine infusion therapy. Your response to treatment will be monitored by your physician and additional treatment recommendations may be made based on your response to IV Ketamine treatment.

For Depression and Other Mental Health Disorders:

Ketamine has been associated with a decrease in symptoms with patients reporting varying lengths and levels of relief. It is difficult to predict how any single person will respond to ketamine infusion therapy. Your response to treatment will be monitored by your physician and additional treatment recommendations may be made based on your response to IV Ketamine treatment.

D. Risk Management

Report any severe or unusual symptoms or side effects at once to the medical staff. Ask the treatment staff if you have any questions regarding the following:

- Your medication
- Your reaction to medication
- Any possible related injury
- Your participation in the clinical treatment

On the day of the infusion, you should **NOT** engage in any of the following after the infusion:

- Driving

- Drinking alcohol or using drugs including marijuana products
- Conducting business
- Participating in activities which require you to rely on motor skills or memory.

E. Voluntary Nature of the Treatment

Undergoing IV Ketamine infusion is entirely voluntary. You are free to choose to receive or not receive the ketamine infusion. Please tell the physician if you do not wish to receive the infusion.

F. Withdrawal of Treatment

Your physician has the right to stop the infusion at any time. He or she may stop the infusion with or without your consent if he or she determines it is necessary to do so in his or her medical judgment.

G. Patient Consent

A physician has discussed with me the above procedure or treatment, the anticipated benefits, likelihood of success, material risks, and side effects. Alternatives and their risks, benefits and side effects have also been discussed as well as declining the above treatment and alternative therapies.

I understand that no guarantees have been made to me regarding the results of this treatment and that it may or may not improve my condition, and that there is unknown safety or long-term effects of Ketamine administration. I have had sufficient opportunity to discuss my condition and treatment with my physicians and all of my questions have been answered to my satisfaction. I believe I have been given sufficient information and adequate knowledge upon which to make an informed decision about undergoing the proposed treatment. I have read and fully understand this form and I voluntarily authorize and consent to this treatment.

I understand that other problems/conditions may develop during the course of treatment that cannot be reasonably foreseen. I authorize Vitalitas Denver physicians to perform such unforeseen procedures or treatments necessary according to his or her medical judgment.

I understand and agree that my consent to treatment is ongoing and includes any and all repeated infusions with Vitalitas Denver.

Patient/Legal
Representative_____Date_____

Print Patient or Legal
Representative_____

Physician Signature_____Date_____

Print Physician
Name_____