

Iowa Ketamine Services, PLC Consent to Treat – Ketamine Infusion

I _____ have been offered a ketamine infusion as treatment for Treatment Refractory Depression and/or Post-Traumatic Stress Disorder.

- I understand that ketamine is not currently FDA approved for this treatment. **Initial here:** _____
- I understand that my insurance will not cover the costs of this treatment. **Initial here:** _____
- I understand that the initial therapy consists of six treatments over 2-4 weeks. However, it is very likely that I will need additional infusions. This will depend entirely on my response to treatment and I will be re-evaluated by Dr. Hodges after each treatment.
- I understand that the average patient may need additional “boosters” of ketamine to maintain response. This will be determined by my treatment course and re-evaluation by Dr. Hodges.
- I understand that the possible side effects during infusion include increased heart rate, transient high blood pressure, feeling “unreal”, mild hallucinations, confusion, blurred vision or general anxiety. These are generally short lived and tolerated well.
- I understand that ketamine is a dissociative anesthetic and may reduce my ability to breath spontaneously. I will therefore be monitored closely during infusion for my safety.
Initial here: _____
- I understand that there are no guarantees concerning my response or rate of relapse. The scientific research on ketamine for this use is still in the early stages. The current data shows ketamine to be safe and quite effective.
- I understand that ketamine is not safe for fetuses or infants. If I am a female of child-bearing age, to the best of my knowledge, I am not pregnant and I am not breastfeeding. If this is of question, I agree to take a pregnancy test prior to my infusion.
- Long term side effects of medical ketamine infusions are not currently known. In the street abuse population, cystitis (bladder irritability) and cognitive impairment (learning and memory problems) have been described.
- I understand that while it is low, there is a potential for addiction for ketamine, even when given in a controlled setting. **Initial here:** _____
- I understand that data concerning my course of treatment and improvement as well as possible adverse reactions will be collected to contribute to possible research.
- I understand that Dr. Hodges may stop the treatment at any time for any reason.
- I understand that in the event of a life-threatening emergency, 911 will be called and I will be transported to the nearest hospital.
- I understand that the alternative to receiving this treatment is to receive no treatment, continue with my current medicines or discuss other medications with my primary provider.

I have read this page in its entirety and understand all aspects of the information presented to me: _____

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Ketamine Infusion

A. Procedures

1. You will be taken to the treatment room in order to receive the drug. You will be accompanied by Dr. Hodges.
2. An intravenous line (IV) will be started in your arm so that you can receive the drug.
 1. I understand that as with any infusion or injection, there is a risk of damage to my skin, blood vessels and nerves, including but not limited to bruising, bleeding, pain, and infection.
 2. **Please initial that you have read the statement 2.1 above:** _____
3. Your heart rate and rhythm will be monitored through electrodes attached to your chest. The level of oxygen in your blood will be checked by a monitor attached to your finger.
4. After completing a questionnaire, under the supervision of a physician, you will receive ketamine through a vein in your arm over the course of approximately 40-60 minutes. Dosing will be discussed with you at your consultation.
5. After receiving the drug, you will be monitored for 10-30 minutes depending on clinical status.
6. Your heart rate and rhythm and blood pressure will be monitored during the infusion as arrhythmias (irregular heartbeats) are a known but rare side effect of ketamine. **Please initial:** _____
7. You will be monitored and then released to the care of a family member or friend. You cannot drive home after the procedure and should not make important decisions or operate complicated machinery for the rest of the day. **Please initial:** _____

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B. Risks/Discomforts

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 (unexpected) risks also may occur.

1. Risk of ketamine
 - a. Side effects normally depend on the dose and how quickly the injection is given. The dose being used is lower than the approved anesthetic doses and will be given slowly over approximately 1-4 hours. These side effects often go away on their own.
2. Side Effects and Incidence by Organ System
 - a. Cardiovascular
 - i. Common (1% to 10%): Blood pressure increased, heart rate increased, increased pulse rate
 - ii. Uncommon (0.1% to 1%): Bradycardia, arrhythmia, hypotension
 - iii. Frequency not reported: Arrhythmia
 - b. Respiratory
 - i. Common (1% to 10%): Respiratory rate increased
 - ii. Uncommon (0.1% to 1%): Respiratory depression, laryngospasm
 - iii. Rare (less than 0.1%): Obstructive airway disorder, apnea
 - c. Ocular
 - i. Common (1% to 10%): Nystagmus, diplopia
 - ii. Frequency not reported: Intraocular pressure increased
 - d. Gastrointestinal
 - i. Common (1% to 10%): Nausea, vomiting, anorexia
 - ii. Rare (less than 0.1%): Salivary hypersecretion
 - e. Musculoskeletal
 - i. Common (1% to 10%): Hypertonia, tonic clonic movements
 - f. Local
 - i. Uncommon (0.1% to 1%): Injection site pain, injection site rash
 - g. Dermatologic
 - i. Common (1% to 10%): Erythema, morbilliform rash

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- h. Psychiatric
 - i. Common (1% to 10%): Hallucination, abnormal dreams, nightmare, confusion, agitation, abnormal behavior
 - ii. Uncommon (0.1% to 1%): Anxiety
 - iii. Rare (less than 0.1%): Delirium, flashback, dysphoria, insomnia, disorientation
 - iv. Frequency not reported: Psychotic episodes
- i. Genitourinary
 - i. Rare (less than 0.1%): Cystitis, hemorrhagic cystitis
- j. Hepatic
 - i. Frequency not reported: Liver function test abnormal
- k. Hypersensitivity
 - i. Common (1% to 10%): Anaphylactic reaction

3. References

- a. 1. Cerner Multum, Inc. "UK Summary of Product Characteristics."
- b. 2. Cerner Multum, Inc. "Australian Product Information."
- c. 3. "Product Information. Ketalar (ketamine)." JHP Pharmaceuticals, Saddle River, NJ.

Ketamine infusion: Other risks

Misuse (drug abuse) of ketamine has been reported in the past. Reports have indicated that ketamine can cause various symptoms, including but not limited to flashbacks, hallucinations, feelings of unhappiness, restlessness, anxiety, insomnia, or disorientation. Individuals with a history of drug misuse or dependence can develop a dependency on ketamine.

Sleepiness: As ketamine is used for sedation in surgery, the doses used in this study may cause sleepiness and may put you to sleep.

Risk of any anesthetic agent: There is a potential risk of dosing error or unknown drug interaction that may cause significant sedation and may require medical intervention including intubation (putting in a breathing tube).

Risk of venipuncture: The risks of drawing blood include temporary discomfort from the needle stick, bruising, and infection. Fainting could also occur.

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Risk of discomfort in answering questionnaires: Some of the questions about your alcohol or drug use and mental health may cause some distress. To minimize discomfort, the questions can proceed at your pace.

Risk of electrocardiographic monitoring or electrocardiogram: To perform this test, we will attach electrodes to the skin of your chest. There is minimal risk involved in this procedure beyond minor discomfort in removing the electrodes.

Risk of other medications: If you are currently taking certain medications on a daily basis within 24 hours prior to and / or after receiving ketamine, you will not be able to take these medication(s) while receiving a ketamine infusion without clearance or approval of the physicians involved in administering ketamine. This is due to concerns for potential increased sedation and / or trouble breathing. Examples include:

- Sedatives (e.g., clonazepam, lorazepam, alprazolam)
- Antibiotics (e.g., azithromycin, clarithromycin)
- Antifungal agents (e.g., ketoconazole)
- Tramadol

Anesthesia: It has been explained to me that all forms of anesthesia, and anesthetic medications, involve some risks and no guarantees or promises can be made concerning the results of my procedure or treatment. Although rare, unexpected severe complications with anesthesia can occur and include the remote possibility of infection, bleeding, drug reactions, blood clots, loss of sensation, loss of limb function, paralysis, stroke, brain damage, heart attack or death. I understand that these risks apply to all forms of anesthesia and that additional or specific risks have been identified above as they may apply to a specific type of anesthesia. **Please initial:** _____

C. Benefits: Ketamine has been shown to improve symptoms of refractory depression, PTSD, OCD, but these effects may not be long-lasting.

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D. Risk Management: You must report any unusual symptoms or side effects at once to the 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 an infusion: You should NOT engage in any of the following:

- Driving
- Drinking alcohol
- Conducting business
- Participating in activities which require you to rely on motor skills and memory. It is very important that you *not be in charge of caring for small children.*

E. Voluntary Nature of Treatment: You are free to choose the ketamine infusion or not. Please tell the doctor if you do not wish to receive the infusion. Not receiving the ketamine infusion does not affect your right to receive any other treatments offered.

F. Withdrawal of Treatment: Your doctor or the treatment staff has the right to stop the treatment at any time. They can stop the infusion with or without your consent for any reason.

G. Patient Consent

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 and 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 have had a chance to ask the doctors and staff questions about this treatment. **Please initial:** _____

They have answered those questions to my satisfaction.

The nature and possible risks of a ketamine infusion have been fully explained to me.

Please initial: _____

The possible alternative methods of treatment, the risks involved, and the possibility of complications have been fully explained to me. **Please initial:** _____

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No guarantees or assurances have been made or given by anyone as to the results that may be obtained. **Please initial:** _____

- I state by my signature below that I have read the information above.
- I know the conditions and procedures of the treatment.
- I know the possible risks and benefits from taking part in this treatment.
- I know that I do not give up my legal rights by signing this form.

I, _____, understand the risks, benefits and alternatives to ketamine therapy as described above and discussed with my provider, Dr. Linda Hodges. I have been given the opportunity to ask questions and receive satisfactory answers regarding ketamine usage. I would like to proceed with ketamine therapy.

Signature _____ Print _____ Date _____

Witness _____ Print _____ Date _____

Provider _____ Print _____ Date _____



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