



# Westchester

## Wellness Medicine

### INFORMED CONSENT FOR KETAMINE INFUSION TO TREAT DEPRESSION

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.

Read the information below closely and discuss it with family and friends if you wish. Ask one of the clinical staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the staff.

Depression can be a severe, recurring, disabling, and life threatening condition. Current medical treatments including but not limited to are only marginally effective. You have chosen this procedure because other treatments have not been successful.

In some studies, ketamine has been shown to provide rapid-acting antidepressant effects from a single infusion. 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. 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

1. You will be taken to the treatment room in order to receive the drug. You will be accompanied by a member of the staff.
2. An intravenous line (IV) will be started in your arm so that you can receive the drug. 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.
3. Under the supervision of a physician, you will receive ketamine through a vein in your arm over the course of approximately 40-60 minutes on one occasion. The dose you receive will be based on your body weight. Most commonly patients receive between 0.5 mg to 2.0 mg of ketamine per kilogram.
4. After receiving the drug, you will be asked to rate the severity of your depression. You may be asked to rate these symptoms at 10, 40, 80, 110, 240, and 360 minutes after infusion. You may also be asked to write a detailed account of your experience later that evening.

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5. 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.
6. 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.

### **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

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 40-60 minutes. These side effects often go away on their own. No lingering effects have been reported.

**Common side effects** (greater than 1% and less than 10%: between 1 out of 100 and 10 out of 100)

- Vivid dreams and nightmares
- Nausea and vomiting
- Increased saliva production
- Blurred vision
- Dizziness
- Out-of-body experience during the infusion
- Increased heart rate during the infusion
- Disrupted motor skills
- Increased blood pressure and increased heart rate (approx. 20% of the normal rate is usual)

The above symptoms will go away when the infusion is stopped, or another medication such as a short acting benzodiazepine may help. **Thus, you should not drive the day of an infusion, but you can drive the following day.**

These two side effects typically happen with high doses

- Increased blood pressure in lungs
- Fast breathing

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**Uncommon side effects** (greater than 0.1% and less than 1%: between 1 out of 1,000 and 10 out of 1,000)

- Jerky arm movements, which resemble a seizure (as a result of increased muscle tension) and cross-eye
- Double vision
- Rash
- Pain and redness in the site of injection • Increased pressure in the eye

**Rare side effects** (greater than 0.01% and less than 0.1%: between 1 out of 10,000 and 10 out of /10,000)

- Allergic reaction
- Irregular heart rate or slow-down of heart rate
- Low blood pressure
- Arrhythmia

### **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.

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

As a result of ketamine you may experience the above reactions and require continued hospitalization for management of your mental and physical health. This medication may not help or even worsen your depression. Experiencing these symptoms may cause you to need medical hospitalization.

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

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.

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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

**C. Benefits** Ketamine has been associated with a decrease in depression symptoms, with results lasting for days to weeks. Ketamine may improve your symptoms of depression, but these effects may not be long-lasting.

### **D. RiskManagement**

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

**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.

**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.

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### G. Patient Consent

I know that ketamine is not a FDA approved treatment for depression. 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 have had a chance to ask the doctors and staff 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 by anyone as to the results that may be obtained.

- 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.

Print Name of Person Obtaining Consent \_\_\_\_\_

Signature of Person Obtaining Consent \_\_\_\_\_ Date \_\_\_\_\_

Print Name of Participant \_\_\_\_\_

Signature of Participant \_\_\_\_\_ Date \_\_\_\_\_