

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

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. 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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4. 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.
5. 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.**

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- Pain and redness in the site of injection
- Increased pressure in the eye

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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. 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.

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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