Navigate Wellness Informed Consent- Ketamine Guided Facilitation

Before you decide to take part in this experience, 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. If there is anything that is unclear or if you would like more details, please ask one of the clinical staff members. 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 clinical staff member.
Depression can be a severe, recurring, disabling, and life threatening condition. You have chosen this therapy 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. Procedure

You will be taken to the journey room in order to receive the drug. You will be accompanied by a staff member.
Under the supervision of a guide, you will take the ketamine that you were prescribed by the prescriber and brought from home. You will be monitored, receive KGF (Ketamine Guided Facilitation) 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/Side Effects /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.

Side effects normally depend on the dose and how quickly the troche 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.

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Common side effects (greater than 1% and less than 10%):

• Vivid dreams and nightmares
• Nausea and vomiting
• Increased saliva production
• Blurred vision
• Dizziness
• Out-of-body experience (s)
• Increased heart rate (approximately 20% of normal rate)
• Disrupted motor skills
• Increased blood pressure

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

These two side effects typically happen with high doses
• Increased blood pressure in lungs
• Fast breathing

Uncommon side effects (greater than 0.1% and less than 1%):
• Jerky arm movements and cross-eye
• Double vision
• Rash
• Pain and redness at the site of injection
• Increased pressure in the eye(s)

Rare side effects (greater than 0.01% and less than 0.1%):

• Allergic reaction
• Irregular heart rate, including 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.

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As ketamine is used for sedation in surgery, the doses used in this procedure 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.

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 Other Medications

If you are currently taking any of the below types of medications on a daily basis or within 24 hours prior to or after receiving ketamine, you will not be able to receive the ketamine infusion without clearance or approval of the provider involved in administering ketamine.

• Sedatives (e.g., Clonazepam, Lorazepam, Alprazolam)
• Antibiotics (e.g., Azithromycin, Clarithromycin)
Antifungal agents (e.g., Ketoconazole)
• Tramadol
This is due to concerns for potential increased sedation and/or trouble breathing.

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. 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 KGF, 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

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E. Voluntary Nature of Treatment

You are free to choose the KGF, or not. Please tell the provider if you do not wish to receive the treatment. Not receiving the ketamine does not affect your right to receive any other treatments offered.

F. Withdrawal of Treatment

Your provider or the treatment staff has the right to stop the treatment at any time. They can stop with or without your consent for any reason.

G. Pregnancy and Breastfeeding

The risks of ketamine use during pregnancy and/or breastfeeding are unknown. For patients who are assigned female at birth or patients who identify as female, you should not undergo ketamine therapy if you are pregnant, breastfeeding, or if there is any chance you may be pregnant.

H. Electronic Appointment Reminders

I consent to have appointment reminders sent to me electronically. If you choose not to receive appointment reminders electronically please let staff know.

I. Veracity

I affirm that the medical history given during the intake process is accurate and complete to the best of my knowledge. I understand that any negative outcome that results from having given inaccurate or incomplete information frees Navigate Wellness Health Group, LLC of all liability.

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L. Patient Consent

I know that ketamine is not a FDA approved treatment for depression. I know that 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 provider or treatment staff may stop the journey at any time without my consent. I know that I have to arrange a ride home and cannot drive for 12 hours after treatment. I have had a chance to ask the provider and staff questions about this treatment.

They have answered those questions to my satisfaction. The nature and possible risks of a ketamine facilitation 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.

_____Signature

_____Print Name_____Date

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