



INFORMED CONSENT TO KETAMINE TREATMENT

This consent form contains information about the use of ketamine therapy for depression and related conditions. Ketamine has been approved by the Food and Drug Administration (FDA) for use as an anesthetic agent for many years. The use of ketamine in lower doses to treat depression is a newer, off-label use of ketamine. This means the FDA does not endorse the use of ketamine for depression, or as a psychotherapeutic agent, and classifies such uses as investigational. Ketamine is not a first-line treatment for depression and is usually used after other treatments have been unsuccessful.

Please 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.

After you understand the risks and benefits of this treatment, you will be asked to sign this form in order to participate. 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.

Procedures

An intravenous line (IV) will be placed in your arm, so you can receive Ketamine. The risk of venipuncture may include temporary discomfort from the needle stick, bruising, blood clots, bleeding, nerve damage, pain, infection and fainting. Your blood pressure, heart rate, and oxygen saturation will all be monitored throughout the infusion under the supervision of a physician.

The dose you will receive will be determined by the physician based on your diagnosis, experience with Ketamine and response to treatments. For the treatment of depression and depressive conditions, patients most commonly receive between 0.5 mg to 2.0 mg of Ketamine per kilogram over 40-60 minutes, followed by a 30-45 minute recovery time (This is

only an estimate and will be individually tailored to each client). For the treatment of chronic pain and related conditions, patients most commonly receive between 50 to 150 mg of Ketamine per hour over four hours, followed by a 1 to 2 hour recovery time.

You will be monitored throughout the infusion process and recovery time 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, drive or operate machinery for the rest of the day.

Risks of Ketamine Infusion

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.

Intravenous (IV) Ketamine Infusion for the treatment of chronic pain disorders or depressive disorders is an off-label use of this drug. There is limited long-term safety and effectiveness data available for use as an antidepressant or for chronic pain. Accordingly, there are potential and currently unknown risks to the administration of Ketamine in repeated doses, and 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 Hot Springs Re-Treat, about your medical history and past or present drug usage, as it may affect your response and safety with IV Ketamine treatment.

Common side effects:

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, increased pressure in the eye, jerky arm movements resembling a seizure. Allergic reaction, irregular or slow heart rate, arrhythmia, low blood pressure, cystitis of the bladder (bladder inflammation, ulcers, and fibrosis). Ketamine can cause various symptoms including, but not limited to flashbacks, hallucinations, and feelings of unhappiness, restlessness, anxiety, insomnia and disorientation.

Individuals with a history of drug misuse or dependence can develop a dependency on ketamine. There is limited information about long-term safety and effectiveness and risk for addiction for 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 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.

Ketamine may not alleviate your symptoms. Ketamine may only temporarily relieve symptoms and may require additional future infusions. Ketamine therapy does not work for everyone and may need to be discontinued due to lack of response to medications, adverse side effects, non-compliance with instructions or for any other reason your physician feels necessary.

Pregnancy

Receiving Ketamine or other drugs during pregnancy may be harmful to a developing fetus. It is the policy of Hot Springs re-Treat that women who are pregnant or breastfeeding or women who may be pregnant should not receive 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. Hot Springs

re-Treat offers women the option to undergo a pregnancy test in our office prior to your infusion.

Voluntary nature of participation

Your decision to undergo ketamine treatment is completely voluntary. Before you make your decision about participation, you may ask and will be encouraged to ask any questions you may have about the process. Withdrawal from ketamine treatment is always your option. Even after agreeing to undergo ketamine treatment, you may decide to withdraw at any time.

Your physician, also has the right to stop the infusion at any time. Physician may stop the infusion with or without your consent if it is necessary to do so on the basis of medical judgment.

Alternatives to ketamine therapy

No other medications or procedures are available to produce the specific effect ketamine provides, though electroconvulsive therapy (ECT) is one alternative in that it may offer a rapid improvement in depressive symptoms.

Confidentiality

Your privacy and all therapy records will be kept confidential. They will be maintained with the same precautions as ordinary medical records. The results of this ketamine therapy may be published in clinical literature. Published reports will not include your name or any other information that would identify you.

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 Hot Springs Re-Treat physicians to perform such unforeseen procedures or treatments necessary according to his or her medical judgment.

PATIENT SIGNATURE _____ DATE _____

PRINTED NAME _____

PHYSICIAN/THERAPIST STATEMENT

I have carefully explained the nature of intravenous ketamine therapy to this patient. I hereby certify that to the best of my knowledge, the individual signing this consent form understands the nature, conditions, risks, and potential benefits involved in participating in ketamine therapy.

PHYSICIAN SIGNATURE _____

DATE _____