

GENERIC KETAMINE THERAPY INFORMED CONSENT

INTRODUCTION

This consent form contains information about the use of subanesthetic ketamine therapy for depression and other conditions of chronic distress.

Ketamine is a novel but not first line treatment for mood disturbances. At the outset we are offering a quote from a very experienced Ketamine clinician that was published in ‘The Ketamine Papers.’

Those who have the most durable responses tend to be the ones who take to heart the message that ketamine is not ‘the thing.’ It is not a magic bullet that will make everything better. Rather, it can be a rapid jump-start on a path to healing and wellness. We strongly advocate continuing with or starting psychotherapy.

Generic ketamine (hereafter in this paper all references to ketamine are to generic ketamine to distinguish it from the FDA approved product Spravado) has been approved by the Food and Drug Administration (FDA) for use as an anesthetic agent for many years. The use of generic ketamine in lower, subanesthetic doses to treat depression is a newer, off-label use of ketamine. This means the FDA does not endorse the use of generic 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. After you understand the risks and benefits of this treatment, you will be asked to sign this form in order to participate. In order for you to decide whether you should undertake this therapy, you should understand enough about its risks and benefits to make an informed decision. This process is known as informed consent.

Ketamine is a novel psychiatric treatment. The primary studies have been with major depressive disorder, bipolar depression, and substance use disorders. While it is not formally approved by the FDA, there are now many studies that demonstrate it may be an effective and rapid treatment option. Benefits may occur after only one treatment, though typically an initial course of several treatments are required for a more robust response. If your depressive symptoms respond to this initial course of ketamine therapy, you may receive further treatments. You may still elect to be treated with other medications and ongoing psychotherapy to try to reduce the possibility of relapse. Over time, you may also need additional periodic ketamine treatments or other therapies to maintain your remission.

Ketamine therapy works best when its use is part of an integrated treatment program including other medications, psychotherapy, and lifestyle changes.

By signing this document you indicate that you understand the information and that you give your consent to the medical procedures to be performed during your participation in ketamine treatment. Please read this consent form carefully, and feel free to ask questions about any of the information in it.

ELIGIBILITY FOR KETAMINE THERAPY

Before participating in ketamine therapy, you will be carefully screened to determine if you are eligible, including a medical history, psychiatric history, and possibly psychological testing. Pregnant women, nursing mothers, and women of child-bearing age who are not using an effective method of birth control should not receive ketamine. If you become pregnant while participating in this program, you should notify your medical providers immediately as the effects of ketamine on the unborn child are undetermined.

OVERVIEW OF SUBANESTHETIC KETAMINE TREATMENT

As part of ketamine administration you will be asked to agree to the following to ensure your safety and well-being:

1. You agree to come to the session with a designated driver to get you home.
2. You agree to remain at the location of the session until the provider decides you are safe to leave.

Driving an automobile or engaging in hazardous activities should not be undertaken until all effects of ketamine have stopped. There is evidence that after 8 hours you should entirely have your faculties. In terms of physical risks, ketamine should not be taken if you have untreated hyperthyroidism or are pregnant of a short term risk of becoming so.

The length of a ketamine session is approximately 1.5 - 2 hours, and you may need to remain in the recovery area for up to an hour following administration. Ketamine can be given as an intravenous (IV) injection or drip, intramuscular (IM) injection, nasal spray, or by mouth.

During your session your medical doctor will be present to make sure you are comfortable and to monitor the procedure. Usually you will remain alert and able to talk during the procedure, but your perception and mental state will be altered by the ketamine.

There is a very helpful description of what Ketamine from 'The Ketamine Papers,' from which I have extracted this quote:

There's a paradox with ketamine. In a couple of ways, it can feel like you're out of control. However, you are fully in control the whole time. You can feel out of control of your body because you feel separated from it. You can also have some physical numbness- usually just toes, fingers, and the area around your mouth-lips-teeth. That combination might lead an unprepared person to believe they can't move. However, you can easily move, and I encourage you to test it out. In fact, even if you needed to get up and walk to the restroom in the middle of a session you could do that. So, it feels like you can't control your body, but you actually can.

The other way people can feel out of control is that there is a natural assumption that the weirdness you feel internally is apparent to an outside observer. This can make some people feel

self-conscious. All outsiders can see is you quietly sitting in a chair. You may feel out of control, but you have full control over what you say, full control over what you do, and you'll have full memory of the events later on.

For most, exposure to ketamine is an interesting and pleasant experience. If your session involves dark or anxious places **these frightening experiences or unpleasant sensations may be of paramount value in your transition to recovery with the help and ongoing guidance from your provider and/or psychotherapist.**

ESTIMATE OF EXPECTED RECOVERY TIME

The non-ordinary state of consciousness produced by ketamine usually lasts approximately 30-45, but can last for one to two hours.

A reduced sense of balance, dizziness, and possible nausea are unusual but can occur.

POTENTIAL RISKS OF SUBANESTHETIC KETAMINE THERAPY

You will be asked to be seated during and after ketamine administration because your sense of balance and coordination will be impaired until the effect has worn off. It is possible you may fall asleep. Other possibilities for adverse effects include blurred and uncomfortable vision, slurred speech, mental confusion, excitability, diminished ability to see things that are actually present, diminished ability to hear or to feel objects accurately including one's own body, anxiety, nausea and vomiting. For the vast majority, intranasal Ketamine sessions are gentle and pleasant.

Rarely, Ketamine can cause the following adverse reactions: tachycardia (elevation of pulse), diplopia (double vision), nystagmus (rapid eye movements), elevation of intraocular pressure (feeling of pressure in the eyes), and anorexia (loss of appetite). The above reactions are

more likely to occur after rapid IV or IM administration of high doses ketamine (in the range of greater than 5 mg/kg, as used for surgical anesthesia). The dose to be used in subanesthetic ketamine therapy is much lower (less than 1.5 mg/kg).

Because of a slight risk of nausea and vomiting, please refrain from heavy eating or drinking for at least the 4 hours preceding the session.

Ketamine can cause a significant increase in blood pressure and heart rate (pulse) which is not a significant issue in health people. You should advise your doctor if you have problems with high blood pressure. Your blood pressure will be checked prior to Ketamine exposure and midway through your Ketamine experience.

Agitation may occur during the course of a ketamine session. We will be with you during your procedure to provide reassurance and assure your safety.

Ketamine has an extensive record of safety and has been used at much higher doses for surgical anesthesia, without respiratory depression. **Untreated**

hypertension is a contraindication to ketamine use as the substance may cause a rise in blood pressure. Similarly, a history of heart disease may make you ineligible to participate.

Repeated, high dose, chronic abuse of ketamine, has been shown to cause urinary tract symptoms and even permanent bladder dysfunction, though in medical use this is rare. In terms of psychological risk, ketamine has been shown to worsen certain psychotic symptoms in people who suffer from schizophrenia or other serious mental disorders, but alternatively has also been occasionally used to successfully treat psychotic depression. It may also worsen underlying psychological problems in people with severe personality disorders. During the experience itself, some people have reported frightening and unusual experiences.

POTENTIAL FOR KETAMINE ABUSE AND PHYSICAL DEPENDENCE

Ketamine belongs to the same group of chemicals as phencyclidine (Sernyl, PCP, "Angel dust"). Collectively, this group is in the chemical class of arylcyclohexylamines, and are further classified as hallucinogens ("psychedelics"). Ketamine is a controlled substance and is subject to Schedule III rules under the Controlled Substance Act of 1970. Medical evidence regarding the issue of drug abuse and dependence suggests that ketamine's abuse potential is equivalent to that of phencyclidine and other hallucinogenic substances, which are low risk in terms of abuse liability. However, cravings have been reported by some individuals and there are documented cases of overuse of illicitly obtained and diverted ketamine. In addition, ketamine can have effects on mood (feelings), cognition (thinking), and perception (imagery) that may make some people want to use it repeatedly. **Therefore, ketamine should never be used except under the direct supervision of a licensed physician.** Such potential for abuse or development of a ketamine use disorder is greater when it is used outside of the office, where there is no monitoring from a physician or other provider.

ALTERNATIVE PROCEDURES AND POSSIBILITIES

No other procedure is available to produce the specific effect ketamine provides, though electroconvulsive therapy (ECT), transcranial magnetic stimulation (TMS), vagal nerve stimulant, and deep brain stimulation (DBS) are alternatives that may offer improvement in depressive symptoms for those with treatment resistant depression. Major depressive disorder (MDD) and bipolar depression, and are optimally treated with a combination of medications and psychotherapy. Specific medication treatment alternatives include augmentation with antipsychotics, thyroid hormone, and bupropion.

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.

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.

INFORMED CONSENT

By signing this form I agree that:

1. I understand that I should not have a heavy meal within 4 hours of my ketamine session.
2. I understand that I need to have someone drive me home from the sessions, and not engage in any driving or hazardous activity for at least 8 hours or more depending on the continued presence of effects after my session has concluded.
3. I have fully read this informed consent form describing subanesthetic ketamine therapy.
4. I have had the opportunity to raise questions and have received satisfactory answers.
5. I fully understand that ketamine sessions can result in a profound change in mental state and may result in unusual psychological and physiological effects.
6. I have been given a signed copy of this informed consent form, which is mine to keep.
7. I understand the risks and benefits, and I freely give my consent to participate.
8. I understand that I may withdraw from ketamine therapy at any time up until the actual injection has been given.

PATIENT SIGNATURE

DATE

PRINTED NAME

PHYSICIAN/THERAPIST STATEMENT

I have carefully explained the nature of subanesthetic ketamine therapy to this patient. 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.

A medical problem or language or educational barrier has not precluded a clear understanding of the subject's involvement in KAP.

PHYSICIAN SIGNATURE

DATE

Reference:

The Ketamine Papers: Science, Therapy, and Transformation. Wolfson and Hartelius Ed., Copyright 2016 MAPS