



KEYSTONE ADVANCED THERAPIES

2208 QUARRY DRIVE, SUITE 200

WEST LAWN, PA 19609

TELEPHONE (610)396-5139 or (610)334-8131 (text line)

fax : (484)509-5141

INFORMED CONSENT FOR IV OR IM KETAMINE THERAPY

This consent form contains information about the use of subanesthetic ketamine therapy for pain or depression. Ketamine has been approved by the FDA for use as an anesthetic agent for many years. The use of ketamine in a lower, subanesthetic dose to treat pain or depression is a newer, off-label use of ketamine and is typically used only after other treatment approaches 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 this treatment. A signed copy of this form is available to you at your request. 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.

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

ELIGIBILITY FOR KETAMINE TREATMENT

Before participating in ketamine treatment, you will be carefully screened using a number of tests and procedures to determine if you are eligible for ketamine therapy, including a medical history, a physical history and examination, a psychiatric history and possibly psychological testing.

Pregnant women and nursing mother must not participate in ketamine treatment. Sexually active women who can have children must utilize birth control methods while participating in the treatment. Ask your primary care physician if you would like to discuss birth control options. If you become pregnant while participating in this program, you should notify your therapist(s) immediately as the effects of ketamine on the unborn child are undetermined.

OVERVIEW OF SUBANESTHETIC KETAMINE THERAPY

During the ketamine administration session, you will be asked to make 2 (two) arrangements with the Doctor to ensure your safety and well being:

1. You agree to follow any direct instructions given to you by the Doctor until it is agreed that the session is over, and

2. You agree to remain at the location of the session until the Doctor and Technician(s) decide you are ready to leave.

The length of the ketamine session will be approximately 90 minutes, and we recommend you remain in the room for at least 30 minutes following the appointment. For IV treatment, an intravenous catheter will be placed, and ketamine is infused over the next 45 minutes at a dose between 0.5 to 2.0 mg/kg body weight. Alternatively, ketamine will be given as an intramuscular injection into your shoulder or buttocks at a dose of 0.5 2 mg/kg body weight. If you become anxious or uncomfortable you may receive a sedative agent Midazolam (Versed) or Propofol (Diprivan), If you become nauseous, you may receive Ondansetron (Zofran), Promethazine (Phenergan), Metoclopramide (Reglan), Famotidine (Pepcid) or Prochlorperazine (Compazine). During the treatment session, the Doctor and Technicians will be present to make sure you are comfortable and to monitor the procedure. A medical professional will be present during the Ketamine administration, and at some other point during the visit to monitor pulse, blood pressure and blood oxygen levels. Usually, you will remain alert and able to speak during the procedure, but your perception and mental state will be altered by the Ketamine. You will return to a normal mental state when the session is over. You will be provided music to make this time more comfortable. When you have returned to your usual state of consciousness, you will share the experience with the staff and Doctor and discuss feedback.

At any time you may ask the staff any questions you may have concerning the procedure or the effects of Ketamine. Your consent to receive Ketamine may be withdrawn, and you may discontinue your participation at any time up until the actual injection has been given.

ESTIMATE OF EXPECTED RECOVERY TIME

The non-ordinary state of consciousness produced by the Ketamine usually lasts about 45-60 minutes, but can last for one to two hours. For some, a reduced sense of balance with dizziness and possibly nausea may occur, and will gradually subside over two to six hour.

POTENTIAL RISKS OF RECOVERY TIME

You will be asked to lie still during the Ketamine administration because your senses of balance and coordination will be very poor until the effect has worn off. Participants have also reported blurred vision, slurred speech, mental confusion, excitability, inability to see things that are actually present, inability to hear or feel objects or one's body, anxiety, nausea and vomiting.

TO MINIMIZE THE LIKELIHOOD OF NAUSEA AND VOMITING, YOU SHOULD NOT EAT A LARGE MEAL DURING THE SIX HOURS PRECEDING THE SESSION.

The administration of Ketamine may also cause the following adverse reactions: tachycardia (elevated pulse), diplopia (double vision), nystagmus (rapid eye movements), elevation of intraocular pressure (feeling pressure in the eyes), and anorexia (loss of appetite). The above reactions occurred after rapid intravenous administration of Ketamine or intramuscular administration of high doses of Ketamine.

Lower urinary tract syndrome (LUTS) is a common condition that has not been reported in Ketamine for depression studies, which used the doses discussed here and used by this office. However, in the abuse population, who typically use very high doses of Ketamine several times per day, this condition is a serious adverse effect. Ketamine abuse can harm the lining of the bladder leading to urinary problems and blood in the urine. If ignored, this condition can progress to scarring in the bladder, obstruction and lead to kidney failure. For these reasons, we use lower doses as infrequently as is needed. Again, this condition has not been reported for doses used in the research done on Ketamine for depression. The doses used in these studies are the basis for our protocol. However, given the seriousness of the condition, it is worth mentioning and could be a risk, especially at higher doses and at greater frequencies. This should be considered when making a decision based on the risks and benefits of this treatment.

Driving an automobile or engaging in hazardous activities should not be undertaken for 24 hours after treatment with Ketamine.

In terms of physical risks, Ketamine should not be taken if you have hyperthyroidism. There have also been reports of some decrease in immune functions in patients receiving surgical doses of Ketamine. It does raise blood pressure, so you should have the approval of your doctor to take Ketamine if you have Hypertension (high blood pressure). However, it has been used for many years as a general anesthetic for children, the elderly, and those with severe physical illnesses because it is considered safer than most general anesthetics.

In terms of psychological risk, Ketamine-induced experience has been shown to worsen certain psychotic symptoms in people who suffer from schizophrenia or other serious mental disorders. It may also worsen underlying psychological problems in people with severe personality disorders. During the experience itself, some people have reported frightening peak experiences. The frightening experiences, however, might be paramount to your transition to recovery with help and ongoing guidance from your therapist.

POTENTIAL FOR KETAMINE ABUSE AND PHYSICAL DEPENDENCE

Ketamine belongs to the same group of chemicals as phencyclidine (aka Sernyl and PCP). This group of chemical compounds is entitled arylcyclohexylamines and is classified as hallucinogens (psychedelics). Ketamine is a controlled substance and is subject to Schedule III abuse and dependence suggest that Ketamine abuse potential is equivalent to that of phencyclidine and other hallucinogenic substances.

With regard to the potential for misuse of Ketamine, "cravings" have been reported by individuals with the history of heavy use of Ketamine and other "psychedelic" drugs. In addition, Ketamine can have effects on mood, cognition, and perception 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.

ALTERNATE PROCEDURES

No other known procedure produces the specific effects of ketamine. Major depression is usually treated with medications and psychotherapy. Subanesthetic Ketamine therapy is a new treatment option when these approaches are unsuccessful. Electroconvulsive therapy (ECT), transcranial magnetic therapy (TMS), and vagal nerve stimulation have also been used for treatment resistant depression. A variety of medications including opiates, anticonvulsant medications, and anti-inflammatory medications have been used for the treatment of pain, and there are a number of alternative techniques such as nerve blocks, physical therapy, infusion pumps, and surgical treatment for various types of pain that do not respond to medications alone. Ketamine may reduce the tolerance that sometimes occurs with opiate medications, and is generally used along with other pain-relieving medications only after the first-line treatment options have failed to successfully control the pain.

CONFIDENTIALITY

Your privacy and all therapy records will be kept confidential. They will be maintained with the same precautions as ordinary medical records. However, health care providers involved in your care will have access to information contained in your record. Privacy and confidentiality of the record will be protected to the extent provided by the law.

The results of the Ketamine therapy may be published. Published reports will not include your name or any other information that could identify you.

INJURIES AND / OR ILLNESS

If you become ill or sustain an injury during your participation in Ketamine Therapy, immediately contact your doctor, and if emergency care is needed, you will be transferred to the closest ER.

VOLUNTARY NATURE OF PARTICIPATION

You should know that the FDA has not yet established the effectiveness of subanesthetic Ketamine therapy. Furthermore, under the Food, Drug and Cosmetic Act, Ketamine is indicated for use only as an anesthetic agent. This means that the FDA doesn't endorse the use of Ketamine as a psychotherapeutic agent or as a treatment for pain and classifies subanesthetic Ketamine therapy as an investigational therapy.

Ketamine therapy is a new treatment for depression and is not a mainstream treatment, though there are several research studies that demonstrate that it can be an effective treatment. The effect generally occurs after several treatments and does not permanently relieve the depression. If the depressive symptoms respond to ketamine, you will still be treated with medications and psychotherapy to try to reduce the rate of relapse. You may also need additional Ketamine treatments or other therapies to maintain remission.

Ketamine infusions generally must be repeated for pain therapy as well in order to maintain response. Sometimes Ketamine taken by mouth or intranasally has been used in attempts to relieve pain or treat

breakthrough pain, but often this approach becomes less effective over time. Ketamine is not generally a first-line treatment for pain as well, and is usually used along with other pain medications that must be continued, and does not produce permanent pain relief.

Your decision to undertake Ketamine Therapy is completely voluntary. Before you make your decision about participating in Ketamine Therapy, your Doctors will give you a chance to ask any questions you may have about the procedure.

INFORMED CONSENT

I understand that I need to have someone drive me home from the treatments, and not engage in any driving activities the day of the treatment.

By signing this form, I agree that:

- I have fully read this informed consent describing subanesthetic Ketamine Therapy
- I have had the opportunity to question the Doctor in charge and received satisfactory answers
- I fully understand that the sessions can result in a profound change in the mental state and may result in unusual psychological and physiological effects.
- I understand that I can request a signed copy of this form at any time
- I understand the risks and benefits, and I freely give my consent to participate in ketamine therapy outlined in this form, under the conditions indicated in it.
- I understand that I may withdraw from ketamine therapy at any time up until the actual injection has been given.
- I have received the pre-treatment and post-treatment instructions.

Signature: _____

Printed name: _____

Date: _____

Physician signature: _____

