

## **Informed Consent for Ketamine Infusion Therapy**

Ketamine injection has been widely used in operating rooms and emergency rooms since it was approved in 1970.

Currently, it is less commonly used as a surgical anesthetic, but is often used as an analgesic in palliative care and other settings.

About 10 years ago, it became known for its remarkable effect on mental illness.

The purpose of use at the ketamine clinic is to treat depression, obsessive-compulsive disorder, PTSD, bipolar disorder, anxiety disorders, chronic pain, and so on.

However, the use of ketamine for the treatment of depression, obsessive-compulsive disorder, PTSD, bipolar disorder, anxiety disorders, and chronic pain is an off-label use and is not currently approved by insurance in Japan.

### **1. Ketamine infusion procedure**

- (1) Intravenous infusions are initiated in the extremities (arms, hands, and feet) to administer ketamine.
- (2) Continuous monitoring of heart rate and oxygen saturation is performed during the infusion.
- (3) Blood pressure will be measured as needed.
- (4) Slowly administer a continuous infusion of ketamine at a dose determined by the physician.
- (4) Adjust subsequent infusion doses according to the infusion response.
- (6) The infusion rate will be adjusted according to the response.
- (7) After the infusion is completed, the patient will be asked to rest for a while.
- (8) If it is determined that going home is not a problem, the patient can go home.

### **2. Risks/side effects**

The risks and side effects of ketamine usually depend on the dosage and the speed of injection.

The dose used for therapeutic purposes for depression, obsessive-compulsive disorder, PTSD, bipolar disorder, anxiety disorders, and chronic pain is the lowest dose that is found to be effective.

The injection rate is adjusted to avoid side effects, although there is a relationship between efficacy and injection rate.

In most cases, side effects are temporary and resolve spontaneously.

Alterations in consciousness caused by ketamine usually last about 30 minutes after the IV injection, but may last longer.

Equilibrium disturbances, dizziness, and nausea may occur, but gradually subside over 3 to 6 hours.

**(1) Common adverse reactions (incidence: those considered more common than 1%)**

- Hallucinations Vivid dreams and nightmares
- Nausea and vomiting
- Increased salivation, dizziness, blurred vision
- Increased heart rate and blood pressure during infusion
- Changes in motor skills

These symptoms usually disappear when the infusion is stopped.

**(2) Rare adverse reactions (incidence: 0.1% to <1%)**

- Rash, diplopia, pain and redness at injection site, increased intraocular pressure, jerking movements of arms similar to seizures

**(3) Extremely rare side effects (incidence: <0.1%)**

- Allergic reactions, irregular or slow heart rate, arrhythmia, hypotension
- The possibility of serious side effects up to and including death, such as anaphylactic shock, cannot be ruled out, but is extremely rare.

**(4) Other Risks**

- Needle sticking may cause temporary discomfort and infection.
- Risk of ketamine interactions with other medications. Disclose all medications (both prescription and over-the-counter), supplements, and other similar items you are taking to your physician.
- Ketamine may not be effective for mental illnesses such as depression, bipolar disorder, PTSD, anxiety, obsessive-compulsive disorder, or chronic pain syndromes.

**3. Indications**

Unlike conventional antidepressants, ketamine has been shown to rapidly decrease symptoms of depression, bipolar disorder, and PTSD.

It has also been shown to help alleviate various chronic pain syndromes and cravings for drugs and alcohol.

An initial series of infusions is used to prolong the duration of improvement.

Although ketamine injection therapy is intended to improve symptoms, its effectiveness is not guaranteed and it is not possible to predict

how people will respond to it.

These effects may not last long and in most cases require further infusions.

Ketamine is not the only option for patients with treatment-resistant depression.

Other options, such as electroconvulsive shock therapy (ECT) and transcranial magnetic stimulation (TMS), are also available.

#### **4. Safety Precautions**

- Do not eat or drink for at least 4 hours prior to the procedure due to the risk of nausea and vomiting. (You may, however, drink water or tea up to 2 hours before.)

Take your regular medications as usual. (Except for Lamictal, benzodiazepines, and sedatives (including narcotic analgesics). Please check with your doctor in advance which medications to take).

- Do not drive a car, operate dangerous equipment, or engage in hazardous activities for 24 hours after the infusion, as reflexes may be dulled or decreased.

It is also recommended that you return home with a companion or escort whenever possible after the infusion.

- Avoid alcohol and other alcoholic beverages before and for 24 hours after the infusion.

- Be sure to inform your doctor about any medications you are taking, especially narcotic analgesics and barbiturates.

- If you have any problems after leaving the clinic, please contact our clinic immediately.

If you cannot contact us directly, please consider consulting or visiting a nearby doctor's office or emergency room.

#### **5. Contraindications to Ketamine Therapy**

Ketamine therapy is not available to individuals with the following conditions/histories

- Aggressive substance abuse or recreational drug purposes

- Schizophrenia or other psychotic disorder (hallucinations, delusions, lack of coherent speech or behavior, or other symptoms that significantly impair reality review)

- Aggressive suicide planning

- History of intracranial hypertension

- Pregnant or lactating mothers

- Uncontrolled hypertension

- Untreated hyperthyroidism

- History of hypersensitivity or negative reaction to ketamine

## **【Ketamine Abuse and Possible Physical Dependence】**

Ketamine belongs to a group of chemicals classified as hallucinogens (“psychedelics”). Ketamine is a controlled substance and is subject to Schedule III regulations in the United States under the Controlled Substances Act of 1970 and has been designated a narcotic in Japan since 2007. There is no evidence that single or repeated doses of ketamine therapy have increased the risk of substance use disorders. There is a low to moderate potential for physical dependence when ketamine is abused as a recreational drug, but the potential for physical dependence is low for medically prescribed ketamine therapy.

## **【Note on suicidal ideation】**

Psychiatric illnesses carry the risk of suicidal ideation (thoughts of ending one’s life). If suicidal thoughts occur before, during, or at any point in the future during the ketamine treatment period, seek emergency medical attention immediately.

## **6. Initiation, continuation, discontinuation, etc. of treatment**

The physician will determine if ketamine treatment is necessary. There is a possibility that you may not be able to receive the infusion even if you wish to, or that the physician may decide to discontinue the infusion at any time or under any circumstances. The patient may also decide to continue or discontinue the ketamine infusion at any time or under any circumstances. If you wish to discontinue the infusion, please notify your physician immediately.

I (the physician in charge) have explained in detail and carefully the nature, conditions, and risks of ketamine therapy as a treatment for depression, OCD, PTSD, bipolar disorder, anxiety disorders, chronic pain, etc., as well as the above mentioned details of each of the multiple treatment modalities and their pros and cons and prognosis to the following patients.

## **7. General Clauses**

All issues related to this treatment shall be governed by the laws of Japan.

The Nagoya District Court shall have exclusive jurisdiction in the first instance over all disputes related to this treatment.

We are not responsible for the legality of ketamine treatment under the laws of your country.

Explanation Doctor Kei Torii

I (the patient) have received a detailed and careful explanation from the above-mentioned physician regarding the nature, conditions, and risks of ketamine therapy as a treatment for depression, OCD, PTSD, bipolar disorder, anxiety disorder, chronic pain, etc., as well as the details of each of the multiple treatment options, their benefits and drawbacks, prognosis, etc., as described above. Based on this information, I would like to apply for ketamine therapy.

Date            /            /            /

Patient Signature \_\_\_\_\_