

# **Policy of Radiation Therapy in Our Hospital**

## **Consent Document**

**Medical Corporation Clinic C4**

## **1. Introduction**

This explanation was prepared to supplement the doctor's explanation and help the patient understand when the patient was treated at the hospital. Please read this explanation carefully, understand it, and make a good decision whether you may receive the treatment of our clinic. If you have difficulty or concerns, please feel free to ask your doctor.

Please read the following instructions carefully, check with your doctor in charge for any questions, and decide whether or not to receive treatment at your own discretion. If you agree, please sign the consent form at the end of this description, date it, and give it to your doctor.

## **2. About your illness**

It is said that one in two people in Japan will develop cancer in their lifetime, so cancer is not a rare disease. There are three main types of treatment for cancer: surgery, radiation therapy, and chemotherapy using anti-cancer drugs. Among these, radiation therapy is an effective treatment that inhibits the growth of cancer cells by irradiating targeted cancer tissues with radiation, but it also causes damage to the surrounding normal tissues. However, it also causes damage to the surrounding normal tissues. To reduce the damage to normal tissues caused by radiation therapy, we use a device called "tomotherapy" for pinpoint irradiation, but this may cause side effects. In order to reduce the symptoms associated with cancer, this hospital offers temporary treatment in a hyperbaric oxygen capsule, but it is not sufficiently effective on its own. Therefore, at this hospital, we are aiming to reduce side effects by combining hyperbaric oxygen capsule therapy with hydrogen gas therapy for patients who have undergone pinpoint radiation.

Hydrogen gas is a gas that exhibits antioxidant, anti-inflammatory, anti-cell lethal, and anti-allergic effects. Theoretically, the antioxidant effect of hydrogen gas is expected to have an effect on hematopoietic dysfunction, which is one of the side effects of radiation, but until now there has been no treatment to see the effect of hydrogen gas on hematopoietic dysfunction caused by radiation. The safety of hydrogen gas has been established through the fact that hydrogen gas has been used in the treatment of bends since ancient times, and we believe that the treatment of cancer patients who have been irradiated with radiation by inhaling hydrogen gas in a hyperbaric oxygen capsule can be a method of reducing side effects.

### **3. Purpose of treatment**

The purpose of the treatment is to examine whether the radiation-irradiated patient can improve the side effects of radiation by inhaling hydrogen gas in a high-pressure oxygen capsule.

### **4. Treatment**

#### **(1) Equipment to be used**

In this treatment, hydrogen gas is inhaled in the high-pressure oxygen capsule in addition to the conventional high pressure oxygen treatment. Hydrogen Gas MiZ Co., Ltd. (Representative Director: Fumitake Sato, 2-47-0056 Ohfune, Kamakura City, Kanagawa Prefecture, Tel: 0467-53-7511) was generated using a hydrogen gas inhaler developed by research and development. Since this hydrogen gas inhaler generates hydrogen by electrolysis of water, and the hydrogen gas is diluted to less than the explosion limit by sending the wind directly to the electrode surface where hydrogen is generated, there is no risk of explosion. In addition, this hydrogen gas inhaler is sold as a health equipment by a distributor of MiZ Corporation, and no health damage from this equipment is recognized.

#### **(2) Treatment method and treatment period**

The time of each radiation is 5-20 minutes, and the number of irradiation times per week is five times in principle, and this schedule is repeated. In addition, after each irradiation, 30 minutes in a high-pressure oxygen capsule, inhales 5% hydrogen gas (4L/min) using a hydrogen gas inhaler installed in a high-pressure oxygen capsule.

Treatment takes into account the condition of the body. If your physical condition changes during treatment and it becomes difficult to inhale hydrogen gas, you may want to stop the treatment at the discretion of your doctor in charge, taking into account the extent to which you are. The treatment can be discontinued at any time at your request.

#### **(3) Predicted therapeutic effects and side effects**

##### **1) Effects**

The expected effect of this treatment is to reduce hematopoietic

dysfunction, such as leukocyte reduction and thrombocytopenia associated with radiation.

## **2) Side effects**

Since hydrogen used in this treatment has been used to treat diving diseases for a long time, the safety of hydrogen gas has been established and we believe that there are no specific side effects. However, there is no denying the possibility of unexpected side effects and side reactions, so we will carefully observe your condition during treatment. If you have any changes or abnormalities, please inform your doctor immediately to respond appropriately.

## **5. Benefits and disadvantages of receiving treatment**

We believe that if you are treated with hydrogen gas, you can expect a higher side effect in addition to conventional treatment. We also hope that the results of this trial will provide information to establish effective treatments for future cancer patients, and we believe that we can contribute to the establishment of more effective treatment methods for cancer.

## **6. Consent and withdrawal of participation**

Whether or not you are eligible for treatment is your own freedom and you value your free judgment. Even if you don't agree, there's nothing at your disadvantage. You are free to cancel your consent after you have agreed, even if you are in the middle of treatment. Please feel free to ask us. In that case, there is no problem in the treatment in the future at all. The doctor in charge will take responsibility and give you the best treatment.

## **7. Discontinuation of treatment**

After you begin the treatment, your doctor may stop treating you. This is discontinued by the doctor in charge if it is determined that continuing treatment has a negative impact on your body, or if you are new to information about the side effects of hydrogen gas and it is deemed necessary to discontinue it. If a clinical trial is cancelled, your doctor will promptly explain to you why.

## **8. Direct browsing of medical history and secondary use of data**

In order to ensure that treatment is carried out in a suitable and safe manner, that the patient's human rights are protected, and that the results of tests and diagnosis are reported correctly, the examiner of the Institute, with the permission of the director of the Institute, we may view medical records such as inspection records directly, but your personal information will be strictly protected.

Also, if your doctor determines that secondary use of the data obtained from this treatment is beneficial, please understand that your data obtained from this treatment may be used. Your personal information will still be strictly protected.

### **9. Protecting your privacy**

Your medical information will be used for research purposes. In addition, the results of the treatment may be used in magazines and academic conferences in Japan and abroad, but no information identifying your name or person will be disclosed, and personal information will be strictly protected, so don't worry.

### **10. In the event of health damage**

If there is a health hazard to you during or after treatment, your doctor will take appropriate medical attention and treatment.

There is no medical expenses or other compensation in the event of a health hazard caused by this treatment. The consent to participate in this treatment does not mean that the patient will waive the right to claim compensation.

### **11. Freedom of questions**

If you have any questions or concerns about this treatment, please ask your doctor if you would like more information.

### **12. What I want you to protect**

1) Please visit the clinic regularly.

Please follow the instructions of your doctor to visit the clinic regularly.

If it is inconvenient, please contact us by phone.

2) Please contact us if you want to use other medicines.

If you have other medications you are currently taking or treatment otherwise as this treatment, be sure to inform your doctor about the treatment. Also, please consult with your doctor about whether or not to continue them. Taking at the same time may have dangerous side effects.

3) Please let us know when your physical condition is different from your usual

If you feel any abnormality in your body during this treatment, please contact your doctor immediately. We will respond appropriately.

4) When the contact is changed

If your address, telephone, or other contact information changes due to moving, please let your doctor know.

5) When transferring to a hospital

If you need to transfer to a hospital or if you wish to transfer to a hospital, please consult your doctor.

6) If you are treated at another hospital during treatment

Please let us know the name of the hospital, the name of the disease, and the name of the drug administered. Please note that we may also inform the hospital that you are participating in this clinical trial or provide your medical information at another hospital.

### **13. Contact information**

If you have any questions about this treatment before you decide to agree to this treatment, or after you have agreed, please ask your doctor at any time.

#### Your doctor in charge

Affiliation: Medical Corporation, Clinic C4

Doctor in charge: Yukimasa Aoki (Director)

Address: 33-12 Motoyoyogi-cho, Shibuya-ku, Tokyo 151-0062

TEL: 03-6407-9407

Have you fully understood the above explanation? If you fully understand

and think that you may participate in this treatment, please fill in the consent date and sign it. I will give you the consent form signed by the doctor in charge.

**Agree**

Medical Corporation Clinic C4  
Yukimasa Aoki, Director

Title: Policy of Radiation Treatment in Our Hospital

**【Patient's Signature Line】**

I was well explained in the treatment. Now that you understand the content of the treatment, i agree on receiving the treatment. You will also receive an explanatory document and a copy of this Agreement.

Consent Date: Heisei Year Date

Patient's name (self-office)\_\_\_\_\_

**【Signature line of the person who accepts it】**

I agree to participate in the treatment because I understand more than just the content of mr. participating in the treatment. You will also receive a copy of the explanatory and consent documents.

Consent Date: Heisei Year Date

Name of the person who accepts the representative (self-office)\_\_\_

**【Signature line of the doctor in charge】**

I agreed to the above patients after explaining this treatment thoroughly.

Date of explanation: Heisei Year Date

Name of explainer (office)\_\_\_\_\_

