Informed Consent Form of The First Affiliated Hospital of Zhengzhou University

Date：May 1st, 2025

NCT:NCT ID not yet assigned

Instructions for Subjects

1.Brief Introduction to the Research Background:

You are invited to participate in a clinical study initiated by the First Affiliated Hospital of Zhengzhou University and chaired by Professor Zheng Yingjuan at our center. This two-year study aims to verify the sonodynamic therapy. It has been reviewed and approved for establishment by the Scientific Research Office of the First Affiliated Hospital of Zhengzhou University and has also obtained the approval of the Ethics Committee of the First Affiliated Hospital of Zhengzhou University to conduct the clinical research.

This informed consent form provides you with relevant information about this clinical study to help you decide whether to participate.

If you agree to participate, please read the following instructions carefully.

If you have any questions, you can consult the researchers in charge of this study.

2.Research Objectives (Brief Background and Significance):

To evaluate the safety and efficacy of sonodynamic therapy combined with radiotherapy and chemotherapy in the treatment of brainstem gliomas, and to explore the clinical problems existing in the treatment process.

3.Research Process and Methods (Brief):

Sonodynamic therapy can significantly inhibit tumor cells through mechanisms such as direct ultrasonic killing of tumor cells, generation of excessive reactive oxygen species, cavitation effects, inhibition of angiogenesis, and anti-tumor immune effects, thereby suppressing tumor growth. This trial plans to recruit 216 newly diagnosed patients with brainstem Diffuse Intrinsic Pontine Glioma (DIPG). The patients will be stratified according to factors such as their basic clinicopathological characteristics and randomly divided into an experimental group and a control group at a 1:1 ratio. Subjects in the experimental group will receive not only SDT but also treatment regimens selected by the researchers, such as radiotherapy, temozolomide, and bevacizumab. Subjects in the control group will only receive the treatment regimens selected by the researchers. The SDT treatment process is as follows: administer "Xipofen" at a dose of 5 mg/kg body weight; start sonodynamic therapy 40 minutes later; place the ultrasonic probe at the positioning point for 15 minutes, twice a day for 4 consecutive days. During the research process, we need to collect some of your specimens, which will be sampled by professionals. For example, we will collect samples for blood routine and liver and kidney function tests. Your samples will only be used for sonodynamic therapy research.

4.Potential Benefits of the Research:

Detecting your specimens can help diagnose the disease, provide necessary treatment recommendations for you, or offer useful information for disease research.

5.Research Risks and Discomforts:

Systemic symptoms such as phototoxic reactions, fatigue, weakness, fever, and pain; skin and mucosal symptoms such as rashes, ulcers, and bleeding; digestive tract symptoms such as diarrhea, nausea, vomiting, anorexia, and melena; respiratory system symptoms such as cough, asthma, hemoptysis, and dyspnea; as well as symptoms of the nervous and cardiovascular systems. In case of photosensitizer allergic reactions, shock, etc., the drug infusion should be stopped immediately, and anti-allergic and anti-shock treatments should be carried out.

6. Other Alternative Treatments:

Chemotherapy; Radiotherapy.

7.Privacy Protection (During the Research Process and in the Publication of Results):

If you decide to participate in this study, your participation in the trial and your personal data during the research will be kept confidential. All information about you will be kept confidential. For example, your blood/urine specimens will be labeled with research numbers instead of your name. Information that can identify your identity will not be

disclosed to members outside the research team unless you give permission. Explain why the identifier must be retained if it is necessary. Indicate when the research materials (written or recorded in other ways) will be destroyed. If the materials are not destroyed at the end of the research, introduce where they will be stored and for how long. Explain how the stored materials will be used in the future and how to obtain the subjects' permission for future use of their materials. All research members and the research sponsor are required to keep your identity confidential. Your files will be stored in the xxx filing cabinet and only accessible to researchers. To ensure that the research is carried out in accordance with the regulations, members of the government regulatory department or the ethics review committee can review your personal data at the research unit as required if necessary.

When the results of this study are published, a commitment to confidentiality is also required.

8.Costs and Compensation:

During your participation in the research, if you suffer research-related injuries, you can receive free treatment and/or corresponding compensation.

9.Voluntary Withdrawal:

As a subject, you can learn about the information and progress of this

research at any time and decide voluntarily whether to (continue to) participate. After participation, regardless of whether an injury occurs or how serious it is, you can choose to notify the researcher at any time to withdraw from the research. The data collected from you after withdrawal will not be included in the research results, and your medical treatment and rights will not be affected. If you continue to participate in the research and suffer serious injuries, the researcher will also stop the research.

If you have questions about the research content, please contact the research doctor at _____; if you have questions related to your rights and interests, you can contact the ethics committee through the contact information at the footer of this informed consent form.

10. Sharing of Research Results after the Study:

When the research is completed and the research product or intervention has been proven to be safe and effective, clarify whether it will be provided to the subjects, when and how it will be provided, and whether payment is required.

Consent Signature Page of the Informed Consent • Form the First Affiliated Hospital of Zhengzhou University

I have carefully read the informed consent form for the clinical study on sonodynamic therapy for brainstem tumors, brainstem gliomas, and recurrent glioblastomas. I had the opportunity to ask questions, and all my questions have been answered. I understand that participation in this trial is voluntary. I can choose not to participate in this trial, or I can withdraw at any time by notifying the researchers without being discriminated against or retaliated against, and my medical treatment and rights will not be affected as a result. If I need other diagnoses/treatments, or if I do not follow the trial plan, or for other reasonable reasons, the researchers may terminate my continued participation in this clinical trial. I voluntarily agree to participate in this clinical trial, and I will receive a signed copy of the "informed consent form".

Please copy: "**I have read and understood this clinical trial and voluntarily agree to participate in it.**"

Subject's Name	
Subject's Signature:	
Subject's ID Number:	
Contact Telephone Number:	
Date:	

(When the subject lacks or has insufficient capacity to provide informed consent, the following methods shall be added or substituted:)

Name of the Guardian：	
Guardian's Signature:	
Guardian's Signature:	
Guardian's Signature	
Contact Telephone Number:	
Date:	

(When the subject or their guardian is illiterate, the following methods shall be added or substituted:)

Name of the Notarized Witness：	
Notarized Witness's Signature:	
Notarized Witness's ID Number:	
Contact Telephone Number:	
Date:	

I have accurately informed the subject of the content of the informed consent form and answered the subject's questions. The subject voluntarily participates in this clinical trial. I have also provided the subject with a signed copy of the informed consent form.

Name of the Research Doctor：	
Research Doctor's Signature:	
Contact Telephone Number:	
Date:	