Informed Consent Form

Official title: The effect of Er,Cr:YSGG laser-assisted topical anesthetic on oral mucosal anesthesia

NCT number: NCT07169032

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You will be invited to participate in a study observing the anesthetic efficacy of the combination of Er,Cr:YSGG laser and surface anesthetic agent on the oral mucosa. This informed consent form provides you with detailed information to help you decide whether to participate in this project. Please read it carefully. If you have any questions, please raise them to the researcher in charge of this study. We will give you a comprehensive explanation.

Your participation in this study is voluntary. This research has been reviewed by the ethics committee of this research institution.

Research purpose: By measuring the anesthetic depth of the combined use of Er,Cr:YSGG water laser and surface anesthetic agent at different time points in the oral vestibule of the maxillary anterior teeth area, to observe the anesthetic efficacy of the combined use of Er,Cr:YSGG water laser and surface anesthetic agent on the oral mucosa.

Research content and process: Before you are selected for the study, the doctor will ask about your basic information, record your medical history, and conduct a routine oral examination. The specific requirements are: no allergy to anesthetic drugs, no mucosal lesions, no pregnancy, no systemic diseases, and good health status.

If you pass the above examinations, you will follow the following steps for the study: Rest for half an hour to stabilize blood pressure and heart rate. The nurse will put an electrocardiogram monitor on you to record the changes in blood pressure and heart rate throughout the process. The doctor will select three sites in the vestibule of the maxillary anterior teeth area and irradiate each site vertically 1 cm away from the site with water laser or ineffective laser for 1 minute, then randomly apply lidocaine or normal saline to the three sites. The subjects will not rinse their mouths during the experiment. The doctor will insert an aseptic needle into three different sites of the mucosa at 10 minutes, 20 minutes, 30 minutes, 40 minutes, and 50 minutes using an

aseptic needle, and the subjects will stop the needle insertion when they raise their hands to indicate "feeling" or "pain". The doctor will record the insertion depth.

After the anesthesia, the doctor will check the wound. The doctor will visit the subject's numbness and record the anesthetic duration. Observe whether there are itching, pain, redness, or swelling at the wound.

Risks and discomforts: A few people in this clinical experiment may experience discomfort symptoms such as itching, pain, and redness. If such discomfort occurs, the doctor will handle it promptly. Your relevant information will be kept confidential. We will do our best to minimize the possibility of your information being exposed.

Benefits of participating in this study: You will receive a free panoramic X-ray, full-mouth examination, and supra-gingival scaling.

Cost: The relevant research costs for this project will be borne by the research group. You do not need to bear the relevant costs required for the research process itself, nor will it increase your additional medical treatment costs. If physical harm is caused to you due to the research itself, the additional medical treatment costs will be compensated or compensated in accordance with relevant national laws and regulations.

As a research subject, you need to: Provide the true information about your medical history and current physical condition; Tell the researcher of any discomfort you experience during this study; Tell the researcher whether you have participated in other studies recently or are currently participating in other studies, and other matters that may affect the research results or your health.

Privacy issue: If you decide to participate in this study, your participation in the trial and your personal information during the trial will be kept confidential. Your identity information will not be disclosed to members outside the research group unless you give your permission. All research members and the research sponsor are required to keep your identity confidential. Your file will be stored in a locked filing cabinet and

only available for researchers to consult. To ensure the research is conducted in accordance with regulations, when necessary, members of government management departments or ethics review committees will be able to consult your personal information at the research institution. When the research results are published, no personal information of you will be disclosed.

You have the right to choose not to participate in this study. During the research process, you also have the right to request to withdraw at any time without any reason. We will decide whether the obtained data will be included in the research results according to your wishes and the needs of the research. Your any rights will not be affected in this case.

If you need other treatments, or you do not follow the research plan, or there is a related injury or any other reasons, the researcher can terminate your participation in this study.

You can always know the information related to you and this study and the progress of the research at any time. If you have any questions related to this study, or you experience any discomfort or injury during the research process, or have any questions regarding the rights of participants in this study, please contact the researcher promptly by phone or other means.

Subject Consent Statement

I have read and fully understood the above introduction about this study, and had the opportunity to discuss this study with the researcher and ask questions. All the questions I raised have received satisfactory answers.

I am aware of the possible risks and benefits of participating in this study. I am aware that participating in the study is completely voluntary.

Subject Signature_____Contact Number:_____Date:_____

Subject's Agent Signature_____Contact Number:_____Date:_____

Researcher Notification Statement

I confirm that I have explained the detailed situation of this study to the subject, including the rights and possible benefits and risks.

Researcher Signature_____Contact Number:_____Date_____

(If the subject is illiterate, a witness signature is required. If the subject has no capacity for action, an agent signature is required.)