Medical Ethics Committee of West China Hospital of Stomatology-Sichuan University

Informed consent for scientific research involving human samples

Study name**: A Prospective controlled clinical trial comparing surgical and conservative treatment in patients with irreducible anterior displacement of the temporomandibular joint disc**

Project No.: **LCYJ2023-YF-1**

Scheme version No.: **LCYJ2023-YF-1-V02**

Informed Consent Version No.: **V03**

Clinical trial institution: □ West China Hospital of Stomatology - Sichuan University

Informed consent form

(Personal reading materials)

Dear subject

You are invited to participate in the "prospective, controlled trial of surgical treatment and conservative treatment for patients with irreducible anterior displacement of the temporomandibular joint disc." Please read this article carefully. Then, you can ask and discuss questions with your family, relatives, friends, or us. This test plan follows the internationally recognized principles of the Helsinki Declaration and the Quality Management Specifications for Clinical Trials of Medical Devices issued by the State Food and Drug Administration to ensure the scientific and reliability of the research and fully protect your rights and interests. The hospital's ethics committee has reviewed and approved for implementation.

The following items describe the test background, purpose, method, benefits brought to you during the test, and possible risks or inconveniences to your rights and interests in the medical device for this test. Please read carefully before you participate in the clinical trial. The information in this Informed Consent Form can help you decide whether to participate in this clinical trial. If you have any questions, please ask the investigator in charge of this trial to ensure you fully understand the relevant content. Whether you participate in this trial is voluntary. If you agree to participate in this clinical trial, please sign in the informed consent statement.

1. Project introduction

The incidence of temporomandibular disorders (TMD) in adults is as high as 8% - 35%. Anterior disc displacement without reduction (ADDWoR) is the main type of late TMD lesions. The main symptoms include pain in the joint area and surrounding muscle tissues and restricted mouth opening, accompanied by tinnitus, hearing loss, migraine, and other symptoms. In severe cases, there may be perforation of the joint disc, bone absorption of

The condyle and other structural changes, and even dental and maxillofacial deformities, significantly impact patients' quality of life.

Currently, there are many clinical diagnosis methods for ADDWoR, including conservative treatment focusing on joint cavity injection, cushion closing, blending, and physiotherapy, and surgical treatment focusing on joint disc reduction and reconstruction. The evaluation of different treatment methods is helpful to explore a perfect clinical diagnosis and treatment sequence of the disease, reduce or even avoid patient illness delay and over-treatment, and also helps to achieve the goal of personalized treatment of precision medicine. However, the number of ADDWoR patients in China is enormous, and the lack of clinical diagnosis and treatment standards leads to patients cannot accept unified and standardized treatment, which increases the psychological and economic burden of patients; At the same time, the differences in treatment concepts also lead to patients' illness delay or excessive medical treatment, increasing the social responsibility. As a large country with ADDWoR in China, starting from the long-term reconstruction of the temporomandibular joint disc and condyle under different treatment modes, our research aims to explore further the indications of different treatment methods for the irreducible anterior displacement of the temporomandibular joint disc, establish the clinical diagnosis and treatment sequence of irreducible anterior displacement of the temporomandibular joint, and standardize the clinical diagnosis and treatment procedures, which will significantly improve the pertinence and effectiveness of our clinicians in the diagnosis and treatment of this disease.

2、 Research purpose

1. To systematically explore the effect of surgical treatment and conservative treatment on the recovery of temporomandibular joint function in adult ADDWoR patients through a large sample prospective controlled trial;

2. To explore the influence of surgical and conservative treatment on the shape and position of the temporomandibular joint disc, the remodeling of joint disc and condyle, and the psychological state of adult ADDWoR patients, and then establish the clinical diagnosis and treatment system of ADDWoR.

3. Research process

1. How many people will participate in this experiment?

About 200 people will participate in this study.

2. Test method and content

Please sign this informed consent form if you agree to participate in this study. This study is a prospective, controlled clinical trial. The subjects in the test group received surgical treatment, while the subjects in the control group received conservative treatment. Before entering this clinical study, after signing the informed consent form, the researcher will conduct a detailed screening of the relevant conditions of the subjects according to the inclusion and exclusion criteria to determine whether they are suitable to participate in this clinical study. After passing the relevant screening, the subject enters the clinical trial.

4. Research steps

1. Test process

Screening → inclusion → surgical treatment/conservative treatment → observation and follow-up → result analysis

- **Screening:** Before you are selected for this study, the physician will record your medical history and conduct a physical, laboratory, imaging examination, and other necessary preoperative examinations to determine whether you can participate. The screening period will be completed within 3 days.
- **Joining the group:** If you do not want to participate in this trial, you will be treated according to your wish. However, if you volunteered to participate in the study and will follow the steps below.
- Patients included in the study will be divided into a surgical and conservative treatment group according to their wishes.

- **Conservative treatment group**

(1) Complete the initial examination and collect data:

MRI and bilateral CBCT small field examination were taken at the initial diagnosis, and temporomandibular joint function assessment, bite force, masticatory efficiency, EMG, and mental health assessment were performed.

(2) Conservative treatment:

Within one month after the diagnosis, an experienced doctor should perform the conservative treatment (occlusal therapy or/an adjustment of the teeth or/and joint cavity injection therapy).

(3) Follow-up after treatment:

MRI was performed at 1 month, 6 months, 12 months, and 24 months after treatment; CBCT examination of the small bilateral field was performed at 6, 12, and 24 months after treatment; The temporomandibular joint function, occlusal force, masticatory efficiency, EMG and mental health were evaluated at 3, 6, 12 and 24 months after treatment.

- **Surgical treatment group**

(1) Complete the initial examination and collect data:

MRI and bilateral CBCT small field examination were taken at the initial diagnosis, and temporomandibular joint function assessment, bite force, masticatory efficiency, EMG, and mental health assessment were performed.

(2) Surgical treatment:

The temporomandibular joint disc will be restored and anchored by an experienced surgeon within 2 months after the diagnosis**.**

(3) Follow-up after treatment:

MRI was performed at 1 month, 6 months, 12 months, and 24 months after treatment; CBCT examination of a small bilateral field was performed at 6, 12, and 24 months after treatment; The temporomandibular joint function, occlusal force, masticatory efficiency, EMG and mental health were evaluated at 3, 6, 12 and 24 months after treatment.

Result analysis: The doctor will provide feedback and collect your clinical situation to judge whether the treatment you receive is safe and effective.

2. Other matters requiring your cooperation

During the clinical observation, you need to receive surgical, conservative, and rehabilitation treatment after treatment according to the doctor's advice. The surgeon will carry out the specific procedures in severe cases through the Clinical Trial Program and clinical operation procedures. According to the doctor's requirements, you should be followed up regularly during the observation period. During the follow-up, please truthfully report your condition changes to your physician so that he can judge whether your treatment is effective and safe.

During your study, you need to:

- Report this medical history and relevant past medical history truthfully, including allergic history.
- Tell the doctor about any health problems you had during the study.
- No drug or treatment other than the research scheme should be carried out.
- Other treatment of the maxillofacial region cannot be carried out by oneself.
- Follow the guidance of researchers and research doctors.
- You can clarify any doubt by directly asking the doctor.
- Actively cooperate to complete the follow-up.

5. Funding source of the test

The fund related to this trial is provided by the "Prospective and controlled trial of surgical treatment and conservative treatment for patients with irreducible anterior displacement of the temporomandibular joint disc" (project No.: LCYJ2023-YF-1).

6. Possible benefits

The surgical or conservative treatment received by the subject is a routine operation. Although there is evidence that surgical or conservative treatment is effective for ADDDoR, it cannot guarantee that it is undoubtedly effective for you. Your condition may be improved, or it may not be improved, or there are the following risks and discomfort.

7. Possible risks or adverse events

Adverse events refer to adverse medical events that occur during clinical trials, regardless of whether they are related to the test medical devices. Although this study's surgical or conservative treatment is effective for ADDWoR, the individual uncertainty of its clinical efficacy still exists, and any treatment may have risks. Any clinical operation or drug application may also have adverse events. Therefore, the risk of adverse events in your participation in the study cannot be ruled out. Some patients occasionally have the following adverse events after surgical treatment: redness and swelling, systemic fever, inflammation, other rejection reactions, local infection, incision dehiscence, etc. Most of these adverse events are closely related to the disease, individual physiological characteristics, and treatment methods. Some patients occasionally have the following adverse events after receiving conservative treatment: 1) local hemorrhage and hematoma; 2) Infection of the wound and surrounding space; 3) The puncture was unsuccessful; 4) Injured local nerves; (such as facial nerve, trigeminal nerve, etc.); 5) Intraarticular hemorrhage and infection; 6) Secondary intracranial injury and internal infection; 7) Secondary pain, mouth limitation, and joint bounce; 8) Injuries to the external auditory canal and middle ear; 9) Injuries to eyeballs and other surrounding tissues; 10) Syncope and allergic reaction; 11) The treatment effect is not ideal and ineffective, or the course of treatment needs to be repeated.

If you have any discomfort in the study, you should contact your physician in time so that he can judge and deal with it promptly.

8. Treatment and economic compensation for test-related injuries

During the study, we will closely monitor adverse events, ensure complete care in postoperative nursing, and take positive measures to prevent them. Furthermore, the orthognathic and joint surgery department of West China Stomatological Hospital of Sichuan University will bear the cost of treatment and corresponding economic compensation for the subjects who have suffered damage related to this according to Chinese laws and regulations.

9. Confidentiality of medical records

We will ensure your privacy as much as possible per the Helsinki Declaration and the Medical Device Clinical Trial Management Specifications. All information about your participation in this study, including your medical history and medical records, will be kept strictly confidential and will not be disclosed to the public under any circumstances. After completing the study, your identity will be held from the research report. To the extent permitted by laws and regulations, relevant medical personnel, members of the Ethics Committee, and representatives of the government administration may check your case records without violating the principle of confidentiality to verify the authenticity, accuracy, and reliability of the research data.

10. Free diagnosis and treatment items and other related subsidies that may be obtained during the trial

According to the clinical application, the standard treatment plan you have received will be checked and treated by a doctor with rich clinical experience who will answer your questions and provide timely and thoughtful medical services. In addition, a subsidy of 500 yuan will be paid to the subjects at the end of the trial. You will not be paid the transportation fees if you do not attend the follow-up visit.

11. Voluntary participation and withdrawal from the test

You can opt out of the study without any punishment and will not lose any benefits you should have obtained. However, if you decide to withdraw from the study during the course of the study, we encourage you to consult with your doctor first. Considering your safety, it is possible to conduct a relevant examination after quitting, and you can choose whether to accept the relevant examination according to your wishes. The examination items include vital signs, specialist examination, laboratory examination, observation index examination, etc. The quitter shall bear the examination costs related to this trial. It is recommended that you carry out the above-related inspections.

If you need another diagnosis/treatment, do not comply with the trial plan, or for any other reasonable reason, the investigator can terminate your continued participation in this trial.

12. Rights and responsibilities of subjects

1. Your rights

You are voluntary throughout the study. If you decide not to participate in this study, it will not affect other treatments you should receive. You will be asked to sign this written informed consent form if you choose to participate. You can withdraw from the trial at any trial stage without discrimination or unfair treatment, and your corresponding medical treatment and rights will not be affected.

2. Your responsibilities

As a subject, you need to provide accurate information about your medical history and current physical condition; Tell the study doctor of any discomfort found during the study; Do not accept the restricted treatment methods, drugs, and food that the doctor has informed you; Tell the study doctor whether he has recently participated in other studies or is currently participating in other studies. If you are a woman of childbearing age, you should strictly abide by the exclusion criteria of this study. During the whole clinical study period, you should not have planned pregnancy.

13. Whom to contact if there are problems or difficulties?

If you have any questions related to this study, don't hesitate to get in touch with your doctor at:

Furthermore, if you have any questions related to your rights/interests, or you want to reflect on the difficulties, dissatisfaction, and concerns encountered in participating in this study, or wish to provide comments and suggestions related to this study, please get in touch with the Hospital Ethics Committee at 028-85501479 or email: hxkqlunli@sina.com。

Finally, thank you again for reading this material. If you decide to participate in this study, please tell your doctor.

Informed consent form (consent signature page)

(Statement of the subject)

I have been informed of this study's purpose, background, process, risks, and benefits. I have enough time and opportunity to ask questions and am very satisfied with the answers. I have also been told whom to contact when I have questions, want to reflect on difficulties, or concerns, research suggestions, get further information or provide assistance.

I have read this informed consent form and agree to participate in this study. However, I can choose not to participate in this study or withdraw from this study at any time during the study without any reason.

I have known that if my condition is worse or I have serious adverse reactions, I have the right to withdraw from this study; Or my research doctor thinks it is not in my best interest to continue to participate in the study, and they will decide to withdraw from the study without my consent; Sponsors or regulators may also terminate the study during the study. If this happens, the doctor will inform me in time, and the research doctor will also discuss my other options.

I will get a copy of this informed consent form containing the researcher's and my signatures. In addition, I will receive a signed copy of the "informed consent form."

Signature of the subject: Date:

Contact information of the subject:

Subject's ID number:

If the subject cannot sign the informed consent due to incapacity or other reasons, or if the subject is a minor, the guardian shall sign.

Signature of guardian: Date:

Relationship with the subject:

The reason why the subject could not sign the informed consent form:

Statement of investigator

I have accurately informed the subjects of the content of the informed consent form and answered their questions. The subjects voluntarily participated in this clinical trial.

Signature of researcher: **Date:**

Contact information of the researcher: