West China Hospital of Stomatology, Medical Ethics Committee Informed Consent Form for Scientific Research Involving Human Samples

Project Name: Multicenter, Prospective, Randomized Controlled Trial of Surgical and Conservative Treatment for Irreducible Anterior Displacement of the Temporomandibular Joint Disc

Project Number: LCYJ-ZD-202302
Protocol Version Number: LCYJ-ZD-202302-V01
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Clinical Trial Institutions:
- West China Hospital of Stomatology, Sichuan University
- Jilin University Stomatological Hospital
- Lanzhou University Stomatological Hospital
- Wuhan University Stomatological Hospital
- Guangzhou Medical University Stomatological Hospital

Informed Consent Form - Personal Reading Material

Dear Participant,

You are invited to participate in the research study titled "Multicenter, Prospective, Randomized Controlled Trial of Surgical and Conservative Treatment for Irreducible Anterior Displacement of the Temporomandibular Joint Disc." Please read this document carefully, and feel free to ask questions and discuss with your family, relatives, friends, or us. This trial protocol adheres to the principles of the internationally recognized Declaration of Helsinki to ensure the scientific integrity and reliability of the research, providing full protection of your personal rights. It has been reviewed and approved by our hospital's ethics committee for implementation.

The following sections detail the background, purpose, methods, benefits, potential risks or inconveniences, and your rights in this trial. Please read carefully before participating in the clinical trial. The information provided in this informed consent form will help you decide whether to participate in this clinical trial. If you have any questions, please ask the researcher responsible for this trial to ensure you fully understand the content. Your participation in this trial is voluntary. If you agree to participate in this clinical trial, please sign the statement in the informed consent form.

1. Project Overview

Temporomandibular joint disorders are among the most common diseases in the oral and maxillofacial area, significantly affecting patients' oral and maxillofacial system functions and even facial morphology. Irreducible anterior displacement of the temporomandibular joint disc (ADDWoR) is one of the most common temporomandibular joint disorders. This disease has a complex course and various treatment methods. Clinical treatments mainly consist of conservative approaches such as oral medications and occlusal splints and surgical treatments focusing on repositioning and anchoring the joint disc. Although both methods are effective, their efficacy, clinical advantages, and disadvantages are still under debate. This study aims to explore the treatment effects of conservative and surgical treatments on ADDWoR through a

multicenter, prospective, randomized controlled study. It aims to explain the impact of different treatment methods on adults with ADDWoR in terms of subjective feelings, joint function, structural repair, and psychological changes, thereby establishing a personalized and standardized ADDWoR diagnosis and treatment system to improve the quality of diagnosis and treatment for temporomandibular joint diseases.

2. Research Objectives

Considering the complexity of ADDWoR progression and unclear treatment standards, this study aims to compare the treatment effects of conservative and surgical treatments on adult ADDWoR through a multicenter, prospective, randomized controlled study. It explores the impact of different treatment methods on adult ADDWoR patients' temporomandibular joint function, joint structural repair, and psychological well-being.

3. Research Process

How many people will participate in this trial?

At least 90 individuals will participate in this study across five different medical institutions.

Trial Methods and Content

If you agree to participate in this study, please sign this informed consent form. For adult ADDWoR patients, the study involves a multicenter, prospective, randomized controlled trial comparing conservative treatment and surgical repositioning. The study will use clinical physical examinations, preoperative and postoperative imaging studies, DC/TMD scoring scales, and other analyses to evaluate objective indicators, subjective experiences, somatic and psychological changes in patients. This will help compare and assess the treatment effects of conservative and open surgical treatments on adult ADDWoR, providing a reliable basis for selecting treatment methods in clinical practice.

If you agree to participate, you will be randomized to receive either conservative treatment (referred to as the "conservative group") or surgical treatment (referred

to as the "surgical group") (T0, treatment plan see Part Four). You will be required to return for follow-up visits and complete questionnaires 1 month (T1), 6 months (T2), 12 months (T3), and 24 months (T4) after the start of treatment. After signing the informed consent form and passing the relevant screening, you will have a 50% chance of being allocated to either the treatment or the surgical group.

4. Treatment Plan

Treatment Process

The conservative treatment includes medication and occlusal splint therapy: Meloxicam (Mobicox) for 2 weeks + symptomatic oral medication, along with wearing a stabilizing occlusal splint for 1 year.

Surgical treatment primarily involves surgical repositioning of the joint disc to restore joint structure and function.

Post-treatment requires six months of mouth-opening training and one year of avoiding hard foods.

Other Requirements for Your Cooperation

During the clinical observation period, you need to follow the doctor's orders for treatment and postoperative rehabilitation training. During the observation period, you should regularly attend follow-ups as required by the doctor. During follow-ups, please report truthfully to your doctor about any changes in your condition to help the doctor determine the effectiveness and safety of your treatment.

During the study period, you will need to:

- Report your current illness and related medical history, including any allergies.
- Inform the doctor of any health problems you experience during the study.
- Avoid any treatments or medications not included in the study protocol.
- Refrain from undergoing any other treatments for the maxillofacial area.
- Follow the guidance and management of the research staff and doctors.
- Ask questions whenever you are unclear about anything.
- Actively cooperate to complete the follow-ups.

5. Funding for the Trial

The funding for this trial is provided by the National Key R&D Program of the Ministry of Science and Technology, "Establishment of a New Clinical Diagnosis and Treatment System for the Temporomandibular Joint" (Project Number: 2023YFC2509200) and "Multicenter, Prospective, Randomized Controlled Trial of Surgical and Conservative Treatment for Irreducible Anterior Displacement of the Temporomandibular Joint Disc" (Project Number: LCYJ-ZD-202302).

6. Risks and Benefits of Participating in This Study

Risks and Strategies:

The risks of this project are the same as those of the treatments themselves. The project team has extensive experience in addressing these risks and has developed corresponding contingency plans.

Patient Benefits:

- Costs related to the study are waived: Medication costs are waived for patients in the conservative group; for patients in the surgical group, the cost of medical consumables for joint disc repositioning and anchoring in surgery is waived.
- All patients are exempt from the cost of specialist examinations and joint function tests before and after treatment.
- All patients are exempt from the cost of imaging studies after treatment (bilateral temporomandibular joint CBCT and open and closed mouth MRI scans).
- Each follow-up visit after the start of treatment will be accompanied by a corresponding transportation subsidy (100 RMB per visit).
- An additional subsidy of 500 RMB after the treatment follow-up.

7. Treatment and Compensation for Trial-Related Injuries

We will closely monitor adverse events during the study, provide proper postoperative care, and take proactive measures for prevention. For participants who suffer harm related to this trial, the researchers will bear the cost of treatment

and corresponding financial compensation in accordance with Chinese laws and regulations.

8. Confidentiality

We will take measures to ensure your privacy rights as much as possible, according to the Declaration of Helsinki. All information about your participation in this study, including your medical history and records, will be kept strictly confidential and will not be disclosed under any circumstances. The report of the study results at the end of the research will not reveal your personal identity. Within the limits allowed by law and regulations, relevant medical personnel, members of the ethics committee, and representatives of government management departments may view your medical records without violating confidentiality principles to verify the authenticity, accuracy, and reliability of the study data.

9. Voluntary Principle

You may choose to withdraw from the study at any time without any penalty and without losing any benefits you are entitled to. If you decide to withdraw from the study, we encourage you to consult with your doctor first. Considering your safety, it is possible that a related examination will be conducted after withdrawal, and you can choose whether to accept the examination based on your wishes. The examination items include vital signs, specialist examinations, laboratory tests, observational indicators, imaging studies, etc. The cost of these trial-related examinations will be borne by the withdrawer. It is recommended that you undergo the above examinations.

If you require other treatments, if you have not followed the trial plan, or for any other reasonable reason, the researchers may terminate your continued participation in this trial.

10. Rights and Responsibilities of the Participants

Your Rights

Throughout your participation in the study you are voluntary. Your decision not to participate in this study will not affect any other treatments you are entitled to. If you decide to participate, you will be asked to sign this written informed consent form. You can withdraw from the trial at any stage without being discriminated against or treated unfairly, and your corresponding medical treatment and rights will not be affected.

Your Responsibilities

As a participant, you need to provide truthful information about your medical history and current health status; tell the research doctor about any discomfort you find during this study; avoid any treatments or medications restricted by the doctor; inform the research doctor if you have recently participated in other studies or are currently participating in other research. If you are a woman of childbearing age, you must strictly adhere to the exclusion criteria of this study and avoid planning or becoming pregnant during the entire clinical study period.

11. Who to Contact if You Have Questions or Difficulties?

If you have any related questions, please contact Dr. ……. Contact Information …….. If you have any questions related to your rights/interests, or if you want to report difficulties, dissatisfaction, and concerns encountered during the participation in this study, or if you want to provide opinions and suggestions related to this study, please contact the hospital ethics committee, phone: 028-85501479, 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

Participant Declaration

I have been informed about this study's purpose, background, process, risks, and benefits. I had enough time and opportunity to ask questions and am satisfied with the answers provided.

I have also been informed about whom to contact when I have questions, want to report difficulties or concerns, have suggestions for the study, wish to obtain further information, or want to provide assistance for the study.

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

I understand that if my condition worsens or if I experience serious adverse reactions, I have the right to withdraw from this study; or if my research doctor feels that continuing the study is not in my best interest, he/she may decide to withdraw me from the study without my consent; the sponsor or regulatory authorities may also terminate the study during its course. If this happens, my doctor will inform me promptly, and my research doctor will discuss other options.

I will receive a copy of this informed consent form with signatures from myself and the researcher. I will receive a signed copy of the "Informed Consent Form."

Participant Signature: date: year month day

Participant ID no:

If the participant cannot sign the informed consent due to lack of capacity to act, or if the participant is a minor, the consent should be signed by their legal guardian.

Guardian's Signature: date: year month day

Relationship to the Participant:

The reason why the participant cannot sign the informed consent form:

I have accurately informed the participant about the contents of the informed consent form and have answered the participant's questions. The participant has voluntarily agreed to participate in this clinical trial.

Researcher's Signature" Researcher's Contact Information

date: year month day