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Multiple-center clinical trial comparing surgical and conservative treatment in patients with anterior temporomandibular disc displacement without reduction

Submission date
17/02/2024

Recruitment status
Recruiting

Registration date
06/03/2024

Overall study status
Ongoing

Last Edited
17/01/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This research focuses on temporomandibular joint anterior disc displacement without reduction (TMJ ADDWoR), a complex jaw joint condition where the disc inside the jaw joint is in the wrong place. The study aims to compare the effectiveness of conservative (non-surgical) treatments and surgical interventions in adult patients with this condition. It seeks to understand how these treatments affect the jaw joint's structure and function, the patient's psychological well-being, and overall facial morphology (face shape).

Who can participate?
Adults aged 18 to 55 years with a first-time occurrence of TMJ ADDWoR

What does the study involve?
Participants are divided into two groups: one receives conservative treatment (like physical therapy, medication, and jaw training), and the other undergoes surgical treatment. The study involves various assessments, including jaw and disc structure analyses and psychological evaluations, conducted at different stages before and after the treatment.

What are the possible benefits and risks of participating?
Participants may benefit from improved jaw function and relief from symptoms. Understanding the effectiveness of different treatments can also guide future TMJ ADDWoR management. Risks might include the typical surgical risks for those in the surgical group and potential discomfort from treatments.

Where is the study run from?
The study is a collaborative effort involving the West China Stomatological Hospital of Sichuan University, Jilin University Stomatology Hospital, Lanzhou University Stomatology Hospital, Wuhan University Stomatology Hospital, and Guangzhou Medical University Stomatology Hospital (China)

When is the study starting and how long is it expected to run for?
June 2023 to December 2026

Who is funding the study?
West China Stomatological Hospital of Sichuan University (China)

Who is the main contact?
Nan Jiang, dent_jn@163.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
WCHSIRB-CT-2023-386

Study information

Scientific Title
A multicenter, prospective, randomized controlled trial of surgical versus conservative treatment in patients with temporomandibular joint anterior displacement without reduction

Acronym
M-PROS-TMAD

Study objectives
Surgical treatment for adult anterior disc displacement without reduction (ADDwoR) is expected to improve subjective feelings, physical and psychological changes, and promote the restoration of the dental system's function and joint structure.

The digital, personalized, and standardized diagnostic and treatment system for adult ADDWoR can effectively reduce surgical trauma and enhance surgical stability.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 30/11/2023, Ethical Committee West China Hospital of Stomatology - Sichuan University (Sichuan Province, Chengdu, 6410001, China; +86 (0)19182163717; waeltelha@163.com), ref: WCHSIRB-CT-2023-386

Study design
Multicenter prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic, Quality of life, Screening, Treatment

Health condition(s) or problem(s) studied
Anterior disc displacement of the temporomandibular joint without reduction

Interventions
Current interventions as of 11/03/2024:
This study is a multicenter, prospective, randomized controlled trial assessing the efficacy of surgical versus conservative treatments in adult temporomandibular joint anterior disc displacement without reduction (TMJ ADDWoR), investigating the effects of surgical and conservative treatments on TMJ function and psychological state in adults with ADDWoR. The study aims to develop a clinical diagnosis and treatment system for ADDWoR by collecting a total of 90 patients from multicenter, controlled trials. Patients are divided into two groups for treatment: conservative and surgical, with follow-ups at 1 , 6, 12, and 24 months.

Randomization:
The researchers employed a robust and transparent method using specialized software designed for clinical trials to randomize participants in their study. After enrolling participants, they input the total participant count into this software, which then randomly allocated them into two distinct groups: one for surgical treatment and another for conservative treatment. This randomization was primarily achieved using a simple yet effective method based on odd and even numbers, which ensured an unbiased and equitable distribution of participants across both treatment arms. The integrity of the randomization process was meticulously documented and monitored throughout the trial to maintain consistency and fairness.

Blinding:
As for blinding, the researchers acknowledge the limitations of their study in this regard. Due to the inherently visible and distinct differences between the surgical and conservative treatment modalities, blinding was not feasible. The participants and the clinicians were unavoidably aware of the treatment being administered. This awareness stems from the physical and procedural distinctions between the two types of interventions, making any form of blinding impossible to implement. The researchers recognize that this aspect could introduce certain biases and have accounted for it in our analysis and interpretation of the study results. These details have been mentioned in the trial protocol.

Conservative treatment group:
1. Physical therapy

2. Pain management: using non-steroidal anti-inflammatory drugs (NSAIDs) to reduce inflammation and pain. muscle relaxants or low-dose antidepressants may be prescribed for pain relief
3. Occlusal appliances (splints or mouth guards)
4. Stress management and relaxation techniques
5. Heat and cold therapy
6. Dietary modifications
7. Education and counseling

Surgical treatment group:
Disc repositioning involves surgical, either open or arthroscopic, alteration or repositioning of the displaced disc to its normal position. The disc may be sutured in place or rigidly fixed using a screw.

Initial assessment: MRI and cone-beam computed tomography systems (CBCT) scans, along with assessments of TMJ function, bite force, masticatory efficiency, electromyography (EMG), and mental health.

Surgical procedure: The TMJ disc is surgically reduced and anchoraged at West China Hospital of Stomatology. Periodic MRI and CBCT scans monitor disc position, morphology, and bony changes in the condyles.

Postoperative evaluation: reassessment of TMJ function, occlusal force, masticatory efficiency, EMG, and mental health at 1, 6, 12, and 24 months postoperatively.

The study's objective is to provide a comprehensive understanding of the impacts and outcomes of these two treatment modalities on ADDWoR.

Previous interventions:
This study is a multicenter, prospective, randomized controlled trial assessing the efficacy of surgical versus conservative treatments in adult temporomandibular joint anterior disc displacement without reduction (TMJ ADDWoR), investigating the effects of surgical and conservative treatments on TMJ function and psychological state in adults with ADDWoR. The study aims to develop a clinical diagnosis and treatment system for ADDWoR by collecting a total of 90 patients from multicenter, controlled trials. Patients are divided into two groups for treatment: conservative and surgical, with follow-ups at 6, 12, and 24 months.

Randomization:
The researchers employed a robust and transparent method using specialized software designed for clinical trials to randomize participants in their study. After enrolling participants, they input the total participant count into this software, which then randomly allocated them into two distinct groups: one for surgical treatment and another for conservative treatment. This randomization was primarily achieved using a simple yet effective method based on odd and even numbers, which ensured an unbiased and equitable distribution of participants across both treatment arms. The integrity of the randomization process was meticulously documented and monitored throughout the trial to maintain consistency and fairness.

Blinding:
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Conservative treatment group:
1. Physical therapy
2. Pain management: use of medications such as non-steroidal anti-inflammatory drugs (NSAIDs) to reduce inflammation and pain. muscle relaxants or low-dose antidepressants may be prescribed for pain relief
3. Occlusal appliances (splints or mouth guards)
4. Stress management and relaxation techniques
5. Heat and cold therapy
6. Dietary modifications
7. Education and counseling

Surgical treatment group:
Disc repositioning: this involves surgical either open or arthroscopic alteration or repositioning of the displaced disc to its normal position. the disc may be sutured in place or rigidly fixed using a screw.

Initial assessment: MRI and cone-beam computed tomography systems (CBCT) scans, along with assessments of TMJ function, bite force, masticatory efficiency, electromyography (EMG), and mental health.

Surgical procedure: surgical reduction and anchorage of the TMJ disc at West China Hospital of Stomatology, followed by periodic MRI and CBCT scans to monitor disc position, morphology, and bony changes in the condyles.

Postoperative evaluation: reassessment of TMJ function, occlusal force, masticatory efficiency, EMG, and mental health at 3, 6, 12, and 24 months postoperatively.

The objective of the study is to provide a comprehensive understanding of the impacts and outcomes of these two treatment modalities on ADDWoR.

Intervention Type
Mixed

Primary outcome(s)
Current primary outcome measures as of 11/03/2024:
1. Morphology, volume, and position analysis of the condyle will be conducted using spiral CT scans and 3D reconstruction software. The volume changes will be compared between different time points at the beginning of treatment T0, 12 months after treatment T3, and 24 months after treatment T4.
2. Analysis of disc morphology and position using MRI scans at different time points, comparing the results using 3D reconstruction software before the start of the treatment T0, one month after treatment T1, six months after treatment T2, and 24 months postoperatively T4.

Previous primary outcome measures:
1. Morphology, volume, and position analysis of the condyle will be conducted using spiral CT scans and 3D reconstruction software. The volume changes will be compared between different time points at 6, 12, and 24 months postoperatively.

2. Analysis of disc morphology and position using MRI scans at different time points, comparing the results using 3D reconstruction software at 6, 12, and 24 months postoperatively.

Key secondary outcome(s))
Current secondary outcome measures as of 11/03/2024:
Psychological state assessment using psychological scales such as General Anxiety Disorder-7 (GAD-7), Patient Health Questionnaire-9 (PHQ-9), and PHQ-15 at T0 before the start of the treatment, 1 month after the treatment T1, 6 month after the treatment T2, 12 months after the treatment T3, and 24 months postoperatively T4.

Previous secondary outcome measures:
Psychological state assessment using psychological scales such as General Anxiety Disorder-7 (GAD-7), Patient Health Questionnaire-9 (PHQ-9), and PHQ-15 at 6, 12, and 24 months postoperatively

Completion date
30/12/2026

Eligibility

Key inclusion criteria
1. Patients with temporomandibular joint anterior disc displacement without reduction (ADDWoR) who have not previously been treated
2. Available and well-preserved clinical data
3. Adults aged 18 to 55 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
All

Key exclusion criteria
1. Presence of biased chewing habits or significant occlusal interference
2. Presence of other severe illnesses or organ dysfunction
3. Incomplete clinical data
4. Individuals under the age of 18 years

Date of first enrolment
07/06/2024

Date of final enrolment
30/12/2026

Locations

Countries of recruitment
China

Study participating centre
West China Stomatological Hospital of Sichuan University
14 3rd Section of Renmin Road South, Wuhou District
Chengdu
China
6410001

Study participating centre
Hospital of Stomatology, Jilin University
No. 1500, Qinghua Road
Chaoyang District
Changchun City
China
130021

Study participating centre
Hospital of Stomatology, Lanzhou University
Lanzhou University Stomatological Hospital is: No. 199, Donggang West Road, Chengguan District
Lanzhou City
China
730010

Study participating centre
Stomatology Hospital, Wuhan University
No. 237, Luoyu Road, Hongshan District
Wuhan City
China
430022

Study participating centre
Southern Medical University Hospital of Stomatology (Guangdong Stomatology Hospital)
No. 1838, Guangzhou Avenue North
Guangzhou City
China
516006

Sponsor information

Organisation
West China Medical Center of Sichuan University

ROR
https://ror.org/040nggs60

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
West China Stomatological Hospital of Sichuan University

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be published as a supplement to the publication of the results.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			26/02/2024	No	Yes
Protocol file			26/02/2024	No	No