ISRCTN18007970 https://doi.org/10.1186/ISRCTN18007970

Clinical trial comparing surgical and conservative treatment in patients with anterior temporomandibular disc displacement without reduction

Submission date
15/01/2023

Recruitment status
No longer recruiting

Registration date
07/02/2023

Overall study status
Completed

Last Edited
08/02/2023

Condition category
Oral Health

[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
The incidence of temporomandibular disorders (TMD; a condition affecting the movement of the jaw) in adults is as high as 8 to 35%. Anterior disc displacement without reduction (ADDWoR) is the main type of late TMD lesions. Currently, there are many treatment 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 number of patients with ADDWoR in China is enormous. In addition, there is a lack of clinical diagnosis and treatment standards, which increases the psychological and economic burden on patients. At the same time, understanding the differences in treatment concepts also leads patients to delay their treatment and the need for excessive medical treatment. Therefore, this study aims to systematically explore the effect of surgical and conservative treatment on the recovery of temporomandibular joint function in adult ADDWoR patients. The large sample prospective controlled study will 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, to finally establish a clinical diagnosis and treatment system for ADDWoR.

Who can participate?
Patients aged 18-45 years old with ADDWoR

What does the study involve?
The patients are divided into conservative and surgical treatment groups. The follow-up for the treatment is 6, 12, and 24 months after either treatment.

What are the possible benefits and risks of participating?
The surgical and conservative treatments received by the subject are routine treatment operations; therefore, any possible post-treatment risks are considered routine too. The department uses the corresponding prevention and rescue measures. If the surgical treatment

causes an allergic reaction and rejection reaction, leading to wound infection and not healing, the anchor nail shall be removed by surgery. Subjects may receive surgical treatment to shorten the treatment time and obtain higher satisfaction. Subjects in both the surgical and conservative treatment groups will receive a subsidy of 500 yuan for participating in and completing this clinical study.

Where is the study run from?
West China Hospital of Stomatology, Sichuan University (China)

When is the study starting, and how long is it expected to run for?
December 2022 to January 2025

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

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
LCYJ2023-YF-1-V02

Study information

Scientific Title
A prospective controlled clinical trial comparing surgical and conservative treatment in patients with irreducible anterior displacement of the temporomandibular joint disc

Study objectives
A study designed to systematically explore the effect of surgical and conservative treatment on the recovery of temporomandibular joint function in adults with anterior disc displacement without reduction through a large sample prospective controlled trial. 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 adults with temporomandibular joint anterior disc displacement without reduction (ADDWoR) and then establish the clinical diagnosis and treatment system of ADDWoR.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/12/2022, Medical Ethics Committee, West China Hospital of Stomatology, Sichuan University (Hospital Management Office, West China Medical Center, Building 1, West China East Campus, no. 28 South Telecom Street, Wuhou District, Chengdu, China; +86 (0)28-85503401; yxglc@scu.edu.cn), ref: WCHS-IRB-CT-2022-504

Study design
Prospective randomized interventional clinical trial study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Temporomandibular joint anterior disc displacement without reduction

Interventions
This study is a prospective, randomized clinical trial study designed to systematically explore the effect of surgical and conservative treatment on the recovery of temporomandibular joint function. The study will also as 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 adults with temporomandibular joint anterior disc displacement without reduction (ADDWoR). The aim of the study is to establish the clinical diagnosis and treatment system of ADDWoR through a large sample prospective controlled trial. The patients are divided into conservative and surgical treatment groups. The follow-up for the treatment is at 6, 12, and 24 months in each group.

The two groups are going to receive a treatment that is either conservative or surgical. Below is the proposed methodology for either group:
1. Conservative treatment group:
1.1. Sodium hyaluronate injection: upper and lower joint cavity injection. After the injection treatment, the patient is instructed to open and close the mouth to distribute the drug in the joint cavity evenly. During the treatment, the patient will be instructed to perform mouth-opening training 100 times daily and bite hard objects. Inject once every 1-2 weeks, 4-5 times in total.
1.2. Stable jaw pads: a transparent resin material to make the jaw stable in which the maxillary

full compression line shall be covered. The jaw plane shall be kept flat. The patient wears the occlusal plate for 24 hours and carries out re-examination and grinding every 2 to 4 weeks. After adaptation, the patient can return once a month. After the occlusion is stable, the occlusal plate is removed for 6 months.
1.3. Accommodation treatment: using red and blue occlusal paper with different thicknesses to determine the occlusal interference points by allowing patients to occlude in the centric, lateral, and protrusive positions repeatedly to confirm the interference points, and finally determine occlusal interference points, adjust and grind occlusal interference points, and restore uniform and non-interference contact of the whole mouth.

2. The surgical treatment group:
2.1. Following the initial diagnosis, MRI and CBCT for bilateral small field examination, temporomandibular joint function assessment, bite force, masticatory efficiency, EMG, and mental health assessment.
2.2. The patients will undergo a surgical reduction and anchorage of the temporomandibular joint disc within 2 months after diagnosis through an endural incision under general anesthesia at west China hospital of stomatology.
2.3. MRI will be performed at 1 month, 6 months, 12 months, and 24 months after postoperatively to confirm the temporomandibular disc position and morphology.
2.4. Similarly, a small bilateral field CBCT examination will be performed at 6 months, 12 months, and 24 months postoperatively for evaluation of the bony changes of the condyles.
2.5. Finally, temporomandibular joint function, occlusal force, masticatory efficiency, EMG, and mental health will be evaluated at 3, 6, 12, and 24 months postoperatively.

Intervention Type
Mixed

Primary outcome(s)
1. Examination of mandibular movement (mouth opening degree, mouth opening type, forward extension, and lateral movement) performed by an inspection measured using a measurement of mouth opening scale at 3 and 6 months
2. Joint murmur, including bounce and friction sound, measured using auscultation at 3 and 6 months
3. Joint area tenderness of the lateral joint capsule, posterior condyle area, condyle going backwards through the external auditory canal measured using palpation at 6 and 12 months
4. Masticatory tenderness (temporal muscle, digastric muscle, medial pterygoid, sternocleidomastoid, and trapezius) measured using palpation at 3 and 6 months
5. Resting and occlusal pain measured using a Visual Analogue Scale (VAS) at 6 and 12 months
6. Morphological analysis of articular disc and analysis of reconstruction of the temporomandibular joint disc measured using MRI examination 6, 12, and 24 months
7. Morphological analysis of temporomandibular joint condyle, and analysis of condylar reconstruction measured using small-field cone beam computed tomography (CBCT) examination at 6, 12, and 24 months

Key secondary outcome(s))
Psychological evaluation of the quality of life measured using the OHI oral health Index at 6 and 12 months

Completion date
31/01/2025

Eligibility

Key inclusion criteria
1. Patients with temporomandibular joint anterior disc displacement without reduction (ADDWoR)
2. Aged 18-45 years old
3. Willing to participate in the clinical study and sign informed consent of meeting the above-mentioned criteria

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
All

Key exclusion criteria
1. Previous treatment for temporomandibular joint disorders
2. Infection, tumor, trauma, and other diseases
3. Jaw deformity, dentition defect, inability to form stable occlusion, and severe occlusion disorder
4. The disc is seriously deformed and perforated, and the operation of the articular disc cannot be performed
5. Immune system disease suffering from rheumatoid arthritis

Date of first enrolment
10/02/2023

Date of final enrolment
01/12/2024

Locations

Countries of recruitment
China

Study participating centre

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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 Hospital, Sichuan University

Alternative Name(s)
West China Hospital, West China School of Medicine and West China Hospital, Sichuan University, WCH, WCSM/WCH

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed 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			30/01/2023	No	Yes
Protocol file	version v.02	25/12/2022	08/02/2023	No	No