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Management of temporomandibular joint arthropathy: comparison of three non-invasive protocols

Submission date
30/04/2024

Recruitment status
No longer recruiting

Registration date
09/09/2024

Overall study status
Completed

Last Edited
09/09/2024

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Temporomandibular joint (TMJ) disc displacement with reduction and intermittent locking is a common issue where the jaw joint's disc moves out of place. This can lead to temporary limited jaw movement but usually resolves without treatment. This study will compare three different treatments to see which is most effective for managing this condition.

Who can participate?
Participants aged 18 years and over with TMJ disc displacement with reduction and intermittent locking

What does the study involve?
Participants are randomly allocated to a standard splint protocol (Group 1), a modified occlusal splint protocol (Group 2), or conventional physical therapy with exercises (Group 3). The first follow-up visit takes place after 1 month of therapy and after 1, 2, 3 and 4 years.

What are the possible benefits and risks of participating?
Participants may benefit from reduced symptoms (pain and intermittent locking). The risks include worsening of symptoms.

Where is the study run from?
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico (Italy)

When is the study starting and how long is it expected to run for?
March 2018 to March 2024

Who is funding the study?
This study was funded by the Italian Ministry of Health – Current Research IRCCS

Who is the main contact?
Prof. Gianluca Martino Tartaglia, gianluca.tartaglia@unimi.it

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Prot. No. 575-2018

Study information

Scientific Title

Comparison of modified occlusal splint and conventional physical therapy in the management of temporomandibular joint disc displacement with reduction and intermittent locking: a randomized controlled trial

Acronym
DDwRwIL management

Study objectives
The modified mandibular splint can be an effective alternative for the treatment of temporomandibular joint (TMJ) disc displacement with reduction and intermittent locking.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/07/2018, Ethics Committee of Area 2 Milano (Via Francesco Sforza, 28, Milano, 20122, Italy; +39 (0)255032982; federica.massacesi@policlinico.mi.it), ref: Prot. No. 575-2018

Study design
Single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Temporomandibular joint disc displacement with reduction and intermittent locking

Interventions
The effectiveness of standard splint protocol (Group 1) modified occlusal splint protocol (Group 2), and conventional physical therapy with exercises (Group 3) will be compared. Patients shall be randomly assigned by computer-generated allocation sequence (1:1) to receive rehabilitation using conventional therapy approaches or modified occlusal splint protocol or disc re-modelling exercises. The first follow-up visit will take place after 1 month of therapy and after 1, 2, 3 and 4 years. Image analysis will involve the evaluation of morphology and function of intra-articular structures. The outcome will be defined as the disappearance of the pain and the intermittent locking.

Intervention Type

Other

Primary outcome measure
Pain at rest and mastication assessed using a Visual Analogue Scale (VAS) from 0 to 10, the extremes of which were ‘no pain’ and ‘pain as bad as the patient ever experienced’ at baseline, 1 year (T1), 2 years (T2), 3 years (T3), 4 years (T4)

Secondary outcome measures
1. Mastication competence assessed using a VAS from 0 to 10, the extremes of which were ‘eating only semi-liquid food’ and ‘eating solid hard food’, at baseline, 1 year (T1), 2 years (T2), 3 years (T3), 4 years (T4)
2. Functional limitation during usual jaw movements assessed using a Likert-type scale (0 - absent, 1 - slight, 2 - moderate, 3 - intense, 4 - severe) at baseline (T0) and the T1 after one year, 2 years (T2), 3 years (T3), and after 4 years (T4)

Overall study start date
18/03/2018

Completion date
18/03/2024

Eligibility

Key inclusion criteria
1. Joint sounds and impairment of jaw movements
2. A positive diagnosis of TMJ disc displacement with reduction and intermittent locking (DDwRwIL) based on clinical inspection
3. Patients of DDwR with intermittent locking confirmed by MRI examination
4. Adults (≥18 years)
5. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
45

Key exclusion criteria

1. Contraindication for MRI (such as patients with any metallic prosthesis or artificial pacemakers)
2. TMJ disc displacement without reduction (DDWoR)
3. Previous facial bone fracture
4. If they had already received any treatment before the MRI

Date of first enrolment
18/10/2018

Date of final enrolment
18/03/2020

Locations

Countries of recruitment
Italy

Study participating centre
Fondazione IRCCS Ca’ Granda Ospedale Maggiore Policlinico
via Francesco Sforza 35
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Sponsor information

Organisation
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

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Sponsor type
Hospital/treatment centre

Website
http://www.policlinico.mi.it/

ROR
https://ror.org/016zn0y21

Funder(s)

Funder type
Government

Funder Name
Ministero della Salute

Alternative Name(s)
Italian Ministry of Health, Italy Ministry of Health, Ministry of Health of Italy, Ministry of Health - Italy, Ministry of Health, Italy

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Italy

Results and Publications

Publication and dissemination plan
The researchers plan to publish the results possibly within 1 year of the study's conclusion

Intention to publish date
18/03/2025

Individual participant data (IPD) sharing plan
The datasets generated during this study will be available upon request from Gianluca Martino Tartaglia (gianluca.tartaglia@unimi.it).
The type of data that will be shared: raw data Excel tables.
Dates of availability: upon publication.
The dataset of the patients has been stripped of any personally identifiable information such as names, addresses and phone numbers.

IPD sharing plan summary
Available on request