

# Occlusal Devices for Restriction of mandibular Movements associated with Temporomandibular joint dysfunction

<b>Submission date</b> 28/07/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/08/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/08/2022	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Anterior disc displacement without reduction (ADDWoR) is a dysfunction affecting the temporomandibular joint (the joint that connects the lower jaw to the skull). It is due to the alteration of the functional relationship between its component structures and it is characterized by restriction in jaw movements and pain. Most patients seek treatment when pain and jaw limitation negatively impact on daily activities and treatment is recommended since it is not self-resolving. Occlusal devices are the most commonly used therapy because most of them lead to a decrease in symptoms through decompression of joint structures and muscle relaxation. However, there are no studies which report the stability of these effects over time, nor guidelines stating which type of device is actually more specific in the treatment of ADDWoR. Therefore, the aim of this study is to compare the effectiveness of two types of occlusal devices already in use in clinical practice.

### Who can participate?

Patients over 18 years old with ADDWoR, which has been present for less than 6 months

### What does the study involve?

Participants are asked to join the study while they are at the Gnathology Service of the Department of Oral and Maxillo-facial Sciences (Sapienza University of Rome), where they are screened by an expert team. They are randomly assigned to one of two treatment groups. Participants in one group will be given the stabilization splint while participants in the other group will be given RA.DI.CA. splint. During the research, participants will undergo five examinations at the clinic. In the first visit, researchers will collect the initial data concerning symptoms and clinical records of mandibular functionality. After this, the device realization procedure is started. Once the device is delivered, it is checked after 1, 3 and 6 months and during these visits the researchers will collect new clinical records to assess any progress. The study lasts about 7 months in total.

### What are the possible benefits and risks of participating?

There are no particular risks involved in this study, other than the fact that there might not be

any significant changes compared to the starting situation. The benefits, on the other hand, can be manifold, such as reduction of joint pain and recovery of joint function, improvement of headaches and/or neck pain.

Where is the study run from?

1. Sapienza University of Rome (Italy)
2. Albanian University (Albania)

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

February 2020 to June 2022

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

1. Dr Paola Di Giacomo, p.digiaco@uniroma1.it
2. Dr Giovanni Falisi, giovanni.falisi@univaq.it
3. Prof. Carlo Di Paolo, carlo.dipaolo@uniroma1.it

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Paola Di Giacomo

**Contact details**

Via Caserta 6

Rome

Italy

00161

+39 (0)644230729

p.digiaco@uniroma1.it

## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

139/22

## Study information

**Scientific Title**

Therapeutic effectiveness of RA.DI.CA. splint versus stabilization splint in subjects with temporomandibular joint closed lock

## **Acronym**

ODRMT

## **Study objectives**

The initial hypothesis is that there are differences in terms of effectiveness between the devices available for the treatment of acute anterior disc displacement without reduction (ADDWoR) of the temporomandibular joint.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 22/02/2022, Institutional Ethics Committee of Albanian University (Faculty of Medical Sciences, Albanian University, Rr Durrësit, Tirane 1001, Albania; Tel: not provided; e. qorri@albanianuniversity.edu.al), ref: 139

## **Study design**

Single-blind randomized study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Acute anterior disc displacement without reduction of temporomandibular joint

## **Interventions**

Patients visiting the Department of Oral and Maxillo-Facial Sciences, Sapienza University of Rome, within a period of 15 months (n = 330) and referring temporomandibular disorders, are screened by expert and calibrated clinicians according to the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD). Sample selection is made according to inclusion and exclusion criteria.

Stabilization splints and RA.DI.CA. splints are compared. Subjects eligible for the study are randomly divided into two groups by a provider not involved in the initial screening and clinical assessments, using a computer-generated blocked random allocation sequence with a block size of 2. Participants are told that they have an equal chance of being assigned to one of the two treatments.

Another provider, blinded to the type of treatment the patient has undergone, will be responsible for data collection at the end of the treatment. The active therapy takes place over about 7 months in total for each subject.

## **Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

RA.DI.CA. splint, stabilization splint

**Primary outcome(s)**

1. Arthralgia, headache and neck pain evaluated using a Verbal Numeric Scale at baseline (T0), after 1 month (T1) and after 6 months (T2)
2. Functional excursions such as mouth opening measured with a gauge and expressed in mm at T0, T1 and T2

**Key secondary outcome(s)**

Evaluation of axis II (psychosocial component) through questionnaires provided by the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) at T0 (baseline), at T1 (1 month after the beginning of therapy) and at T2 (6 months after the start of therapy)

**Completion date**

21/06/2022

**Eligibility****Key inclusion criteria**

1. Patients over 18 years old
2. Diagnosis of jaw functional limitation due to unilateral disc displacement without reduction for less than 6 months, verified in magnetic resonance imaging (MRI), according to Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) and DC/TMD criteria

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

30

**Key exclusion criteria**

1. Jaw limitation due to other factors such as connective tissue diseases (scleroderma), traumas (mandibular or condylar fractures), deformities, tumors, temporomandibular joint (TMJ)

ankylosis, muscular locking

2. Other concomitant conservative therapies such as physical rehabilitation

**Date of first enrolment**

01/07/2020

**Date of final enrolment**

02/05/2022

## **Locations**

**Countries of recruitment**

Italy

**Study participating centre**

**Sapienza University of Rome**

Department of Oral and Maxilla-Facial Sciences

Via Caserta 6

Rome

Italy

00161

## **Sponsor information**

**Organisation**

Sapienza University of Rome

**ROR**

<https://ror.org/02be6w209>

## **Funder(s)**

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes