ISRCTN77777174 https://doi.org/10.1186/ISRCTN77777174

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

Submission date
28/07/2022

Recruitment status
No longer recruiting

Registration date
01/08/2022

Overall study status
Completed

Last Edited
01/08/2022

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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.digiacomo@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.digiacomo@uniroma1.it

Additional identifiers

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 Durresit, Tirane 1001, Albania; Tel: not provided; e. qorri@albanianuniveristy.edu.al), ref: 139

Primary study design
Interventional

Study design
Single-blind randomized study

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