Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the Effect of Different Thickness of Soft and Hard Occlusal Splints on Reducing Clinical Symptoms in Patients with Temporomandibular Joint Disorders Referring to the Occlusion department of Mashhad Dental School in 1397

Protocol summary

Study aim

Comparison of the Effect of Different Thickness of Soft and Hard Occlusal Splints on Reducing Clinical Symptoms in Patients with Temporomandibular Joint Disorders Referring to the Occlusion department of Mashhad Dental School in 1397

Design

The randomization method will be in this way: a packet of 60 numbers will be given to the secretary. The patient and the secretary do not know what treatment method is for each number. The patient chooses a therapeutic approach by receiving a secretary's number.

Settings and conduct

In this study, 60 patients from Mashhad Dental School who have Criteria for entering/ exiting study and matched for age and sex are randomly assigned to the four groups. In this study, before splint application, after 1 week, 1 month and 3 months, patients will be examined for pain and maximal oral opening. In the Visual Analogue Scale (VAS), the patient is given a score of 0 to 10 points to assess the pain depending on the behavior, movements, state, and... Blinding in this study is not feasible due to the goals and method of implementation, but in order to avoid the bias in the outcome, the patients' follow up is done by the executor of the project that does not know the type of treatment for each patient.

Participants/Inclusion and exclusion criteria

Patients referring to the Department of Occlusion at Mashhad Dental School who completed the informed consent form Patients with RDC1 and RDC3 with pain based RDC/TMD Patients over the age of 18 and under age 50 Skeletal Class 1 Patients History of trauma in the last 3 months has not been to the joint, face or neck.

Intervention groups

soft occlusal splint 1 mm thickness soft occlusal splint 3 mm thickness hard occlusal splint 1 mm thickness hard occlusal splint 3 mm thickness

Main outcome variables

Pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180513039631N1**
Registration date: **2019-01-05, 1397/10/15**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-05, 1397/10/15**
Update count: **0**

Registration date

2019-01-05, 1397/10/15

Registrant information

Name

mohammad bagheri Iraj

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3804 9292

Email address

bagherimh951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-31, 1397/03/10

Expected recruitment end date

2019-05-31, 1398/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Different Thickness of Soft and Hard Occlusal Splints on Reducing Clinical Symptoms in Patients with Temporomandibular Joint Disorders Referring to the Occlusion department of Mashhad Dental School in 1397

Public title

Comparison of the Effect of Different Thickness of Soft and Hard Occlusal Splints on Reducing Clinical Symptoms in Patients with Temporomandibular Joint Disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients referring to the Department of Occlusion at Mashhad Dental School who completed the informed consent form Patients with RDC1 and RDC3 with pain based RDC/TMD Patients over the age of 18 and under age 50 skeletal Class 1 Patients history of trauma in the last 3 months has not been to the joint, face or neck.

Exclusion criteria:

Patients with uncontrolled systemic disease Patients with nerve disorders, head and neck cancer Edentulous patients Patients with history of TMJ surgery Patients with idiopathic clinical symptoms

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method will be in this way, a packet with 60 number, available to the secretary.The patient and the secretary do not know what numbers are for study groups. The patient chooses a therapeutic approach by receiving a number.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants do not know the type of treatment they were given include thickness and the type of occlusal splints.A researcher who is responsible for the patient's fallow up do not Know type of treatment for each patient. Also, data analyzer do not aware from the study groups and the type of treatment received by each patient.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Vakil Abad- In front of Mellat Park, Faculty of Dentistry

City

mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2018-04-18, 1397/01/29

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1397.002

Health conditions studied

1

Description of health condition studied

temporpmandibular disorders

ICD-10 code

M99

ICD-10 code description

Biomechanical lesions, not elsewhere classified

Primary outcomes

1

Description

Pain score

Timepoint

before study, 7th, 30th, 90th day after Therapeutic intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: soft occlusal splint 1 mm thickness. The criterion for making occlusal splints is in this way: at first, the distance between the lower right central incisor cervical point (if its absence, use lower left central incisor) and incisal edge right upper central incisor is measured in the absence of splint. then, with occlusal splints, the distance is re-measured. Soft occlusal splints with 1 mm thickness are made of elastic rubbery sheets with a thickness of 1 mm. In this study, before splint application, after 1 week, 1 month and 3 months, patients will be examined for pain and maximal oral opening.

Category

Treatment - Devices

2

Description

Intervention group: soft occlusal splint 3 mm thickness. The criterion for making occlusal splints is in this way: at first, the distance between the lower right central incisor cervical point (if its absence, use lower left central incisor) and incisal edge right upper central incisor is measured in the absence of splint. then, with occlusal splints, the distance is re-measured. Soft occlusal splints with 3 mm thickness are made of elastic rubbery sheets with a thickness of 3 mm. In this study, before splint application, after 1 week, 1 month and 3 months, patients will be examined for pain and maximal oral opening.

Category

Treatment - Devices

3

Description

Intervention group: hard occlusal splint 1 mm thickness.The criterion for making occlusal splints is in this way: at first, the distance between the lower right central incisor cervical point (if its absence, use lower left central incisor) and incisal edge right upper central incisor is measured in the absence of splint. then, with occlusal splints, the distance is re-measured. Hard occlusal splints are made of acrylic resin with 1 mm thickness. In this study, before splint application, after 1 week, 1 month and 3 months, patients will be examined for pain and maximal oral opening.

Category

Treatment - Devices

4

Description

Intervention group: hard occlusal splint 3 mm thickness. The criterion for making occlusal splints is in this way: at first, the distance between the lower right central incisor cervical point (if its absence, use lower left central incisor) and incisal edge right upper central incisor is measured in the absence of splint. then, with occlusal splints, the distance is re-measured. Hard occlusal splints are made of acrylic resin with 3 mm thickness. In this study, before splint application, after 1 week, 1 month and 3 months, patients will be examined for pain and maximal oral opening.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Mashhad University of Medical Sciences

Full name of responsible person

Azam Sadat Madani

Street address

Vakil Abad, In front of Mellat Park, Faculty of Dentistry

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Email

madania@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohammad Bagheri Iraj
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
Azam sadat Madani
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Professor
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Person responsible for updating data

Contact
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Full name of responsible person
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Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The total potential data can be shared after unidentifiable people
When the data will become available and for how long
Starting the access period from 2020
To whom data/document is available
Researchers People who are engaged in the industry
Under which criteria data/document could be used
Sending a request for access to data, or documentation and analyzes permissible on delivered data must be notified by email to the corresponding author
From where data/document is obtainable
corresponding author, Mohammad Bagheri iraj, mohammad.b.iraj@gmail.com
What processes are involved for a request to access

data/document

Sending a request for access to data, or documentation must be notified by email to the corresponding author

We try to provide the data applicant in less than a month to the requesting researcher.

Comments