

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparing the treatment efficacy of splint and electrical stimulating on temporomandibular joint disorders

Protocol summary

Summary

This is a randomized clinical trial aimed to compare the treatment efficacy of splint and electrical stimulation on temporomandibular joint disorders in 40 patients suffering from temporomandibular joint disorders in 2016-2017. Inclusion criteria are age of 16-45 years, having normal teeth except the third molar tooth and Angle Class I occlusion and having occlusal interferences and exclusion criteria are having systemic disease, organic disorders of temporomandibular joint, using antipsychotic drugs within the last two weeks, history of orthodontic treatment and having any prosthesis. After inclusion in the study, the patients will be randomly divided into two equal groups, splint group and electrical stimulation group. Patients in the splint group will be given a maxillary occlusal splint and they will use it for 8 weeks; in the first 6 weeks they will use it 24 hours a day and from the 6th week till the end of the 8th week its usage will be reduced so that at the end of the 8th week they will use it only while sleeping; at the end of the 8th week the mean pain score will be calculated using Visual Analog Scale. In the electrical stimulation group, the patients will receive 10 sessions of treatment through stimulation of the skin of the temporomandibular joint area; each session will last 30 minutes with a frequency of 80 Hz; at the end of the 10th session the mean pain score will be calculated using Visual Analog Scale. Finally, the data will be compared together.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110730761N1**

Registration date: **2016-12-15, 1395/09/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-15, 1395/09/25

Registrant information

Name

sirous risbaf fakour

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3341 4003

Email address

s_risbaf@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the treatment efficacy of splint and electrical stimulating on temporomandibular joint disorders

Public title

The effect of splint and electrical stimulating on temporomandibular joint disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 16-45 years; having normal teeth except the third molar tooth and Angle Class I occlusion and having occlusal interferences. Exclusion criteria: having systemic disease; organic disorders of temporomandibular joint; using antipsychotic drugs within the last two weeks; history of orthodontic treatment and having any prosthesis.

Age

From **16 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

We will use the random number table for randomization of the patients. In this table, even numbers will be assigned to splint group and odd numbers to electrical stimulation group; reading direction of the numbers will be left-to-right.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences and Health Services campus, Khaliye Fars Blv, Doctor Hesabi Sq, Zahedan

City

Zahedan

Postal code

Approval date

2016-10-23, 1395/08/02

Ethics committee reference number

ir.zaums.rec.1395.189

Health conditions studied

1

Description of health condition studied

Temporomandibular joint disorders

ICD-10 code

K07.6

ICD-10 code description

Temporomandibular joint disorders

Primary outcomes

1

Description

mean pain score

Timepoint

at the end of 8th week in the splint group and at the end of 10th session in the electrical stimulation group

Method of measurement

Using Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

Splint group: Using splint for 8 weeks; in the first 6 weeks it will be used 24 hours a day and from the 6th week till the end of the 8th week its usage will be reduced so at the end of 8th week it will be used only while sleeping

Category

Treatment - Other

2

Description

Electrical stimulation group: the patients will receive 10 sessions of treatment through stimulation of the skin of the temporomandibular joint area; each session will last 30 minutes with a frequency of 80 Hz

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan University of Medical Sciences

Full name of responsible person

Mostafa Ghayoor

Street address

Zahedan University of Medical Sciences and Health Services campus, Khaliye Fars Blv, Doctor Hesabi Sq, Zahedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zahedan University of Medical Sciences

Full name of responsible person

Hoshang Rafighdoost

Street address

Deputy of research and technology, Zahedan University of Medical Sciences campus, Jannat Blv, Zahedan

City

Zahedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Mostafa Ghayoor

Position

Dentistry Student

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Person responsible for scientific inquiries

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Person responsible for updating data

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Position

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary
empty