Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of Parafunctional Habitual Deletion in Improvement of Patient with Temporomandibular Joint Disorder and Neck Pain

Protocol summary

Summary
This study aimed to assess the efficacy of elimination of oral parafunctional habits for improvement of TMDs and neck pain. This interventional study was conducted on 136 patients presenting to the oral medicine department from January 2012 to January 2014 who had TMD, parafunctional habits and neck pain according to the Helkimo's index and the neck pain and disability index (NPDI). Patients were instructed on how to quit their parafunctional habits and were followed up at one and two months.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT201410091559N6**
Registration date: **2016-02-18, 1394/11/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2016-02-18, 1394/11/29

Registrant information
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Recruitment status
Recruitment complete

Funding source
Oral and Maxillofacial Medicine Departments of Tehran University of Medical Sciences

Expected recruitment start date
2013-01-09, 1391/10/20
Expected recruitment end date
2015-01-25, 1393/11/05
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Parafunctional Habitual Deletion in Improvement of Patient with Temporomandibular Joint Disorder and Neck Pain

Public title
Elimination of Parafunctional Habits for Treatment of Temporomandibular Disorders and Neck Pains
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients who had TMDs according to the Helkimo's index; Patients who had parafunctional habits along with TMDs; Patients who had neck pain according to the criteria described by NPDI; Subjects between 15 to 75 years; Exclusion criteria: Subjects who only had TMDs or neck pain; Subjects younger than 15 or older than 75 years; Subjects with a history of trauma to their neck or TMJs; Subjects who were under regular pharmaceutical therapy for TMDs and neck pain.
Age
From **15 years** old to **75 years** old
Gender
Both

Phase
N/A

Groups that have been masked
No information
Sample size
Target sample size: **136**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shcool of Dentistry, Tehran Univrsity of Medical Sciences
Street address
School of Dentistry, Tehran University of Medical Sciences, North Karegar St., Enghelab Sq., Tehran.
City
Tehran
Postal code
Approval date
2015-12-21, 1394/09/30
Ethics committee reference number
IR.Tums.REC.139401451

Health conditions studied

1

Description of health condition studied
TMD, Neck pain
ICD-10 code
K07.6, S14
ICD-10 code description
Temporomandibular joint disorders, Injury of cervical sympathetic nerves

Primary outcomes

1

Description
TMD
Timepoint
at the time of intervention,,1months after intervention...and 2months after intervention
Method of measurement
Helkimo index

Secondary outcomes

1

Description
Neck pain
Timepoint
at the time of intervention,,1month after intervention...and 2months after intervention
Method of measurement
NPDI index

Intervention groups

1

Description
Patients were instructed to place their tongue behind their maxillary central incisors in such a way that the tongue applied no pressure to oral and dental tissues (as when the letter N is pronounced). In this position, the distance between the upper and lower teeth must be a few millimeters and lips must be closed with minimal pressure. In this position, the freeway space is maintained.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Oral and Maxillofacial Medicine Departments of Tehran University of Medical Sciences
Full name of responsible person
Ẹlahe Mostajir
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Center of School of Dentistry, Tehran University of Medical Seiences
Full name of responsible person
Dr. Zahra Khorshidi
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Research Center of School of Dentistry, Tehran University of Medical Sciences, Enghelab Sq., Tehran.
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Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Center of School of Dentistry, Tehran University of Medical Seiences
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

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Person responsible for updating data

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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