

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparation Evaluation of effect of low-level laser therapy and drug on temporomandibular joint disorders

Protocol summary

Study aim

Comparision of low level laser therapy and medicine treatment efficiency on temporomandibular joint disorders

Design

The controlled clinical trials, community-based and pragmatic, parallel group, randomized, Sample size 42 patients with TMD

Settings and conduct

42 patients with Temporomandibular joint disorder were selected from patients admitted to Oral and maxillofacial surgery department of Zahedan university of medical sciences. They were divided into 2 group randomly . Laser group patients were treated with low level laser and control group were treated with medicine.

Participants/Inclusion and exclusion criteria

15 to 45 years old patients that have at least one of TMD criteria

Intervention groups

1-Low level laser therapy : The patient were treated for a period of one month, three times a week with a low-level laser. 2-Drug treatment: The patient were received a megafen drug for 5 days, three times a day.

Main outcome variables

Mean score for pain ; Mean score for pain in touch; Mean size of mouth maximum opening ; Clicking

General information

Reason for update

Acronym

TMD : Temporomandibular joint disorder

IRCT registration information

IRCT registration number: **IRCT20161107030761N3**

Registration date: **2018-02-08, 1396/11/19**

Registration timing: **retrospective**

Last update: **2018-02-08, 1396/11/19**

Update count: **0**

Registration date

2018-02-08, 1396/11/19

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

Personal

Expected recruitment start date

2017-09-06, 1396/06/15

Expected recruitment end date

2017-11-06, 1396/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparation Evaluation of effect of low-level laser therapy and drug on temporomandibular joint disorders

Public title

Effect of laser and drugs on temporomandibular joint disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 15 to 45 years old Pain of temporomandibular joint region Limit of oral maximum opening Limit of mandible lateral movement Clicking

Exclusion criteria:

Systemic disease History of trauma or surgery in temporomandibular joint region No patient cooperation

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Flip a coin were used to randomize samples.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zahedan University of Medical Sciences

Street address

East Azadegan Ave., Dental School

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817699693

Approval date

2017-11-26, 1396/09/05

Ethics committee reference number

IR.ZAUMS.REC.1396.247

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

first visit, one week later, two weeks later and four weeks later

Method of measurement

Using visual analog scale

2**Description**

Clicking

Timepoint

first visit, one week later, two weeks later and four weeks later

Method of measurement

Using Stethoscope while opening of the mouth

3**Description**

Limit of mouth opening

Timepoint

first visit, one week later, two weeks later and four weeks later

Method of measurement

Measuring of maximum mouth opening by ruler

4**Description**

Touch sensitivity

Timepoint

first visit, one week later, two weeks later and four weeks later

Method of measurement

By touch of maseter and temporalis muscles and temporomandibular joint.

Secondary outcomes

empty

Intervention groups**1****Description**

Laser group: After first visit, 4 points around the joint will be radiated by a diode laser fo 40 seconds and this treatment will go on fo 4 weeks(3 time a week) .

Category

Treatment - Other

2

Description

Treatment by drug group: After first visit, 15 capsules of megaphen as 3 in a day will be prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan university of medical sciences

Full name of responsible person

Sirous Risbaf fakour

Street address

College of dentistry , Eastern Azadegan St. , Zahedan City

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817699693

Phone

+98 54 3344 1814

Email

s-risbaf@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Nourmohammad Bakhshani

Street address

ZaUMS Main campus, Jenat Blvd., Zahedan, Sistan and Baluchestan, Iran

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3342 5765

Email

nmbakhsha@zdmv.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan university of medical sciences

Full name of responsible person

Niloufar Ghodousi

Position

Dentistry student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

College of dentistry , Eastern Azadegan St. Zahedan city

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817699693

Phone

+98 54 3329 5715

Fax

Email

Niloufar.qodoosi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Sirous Risbaf Fakour

Position

Oral and maxillofacial surgon

Latest degree

Specialist

Other areas of specialty/work

Oral and maxillofacial surgery

Street address

East Azadegan st. - Kooye tir andazi - zahedan college of dentistry

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817699693

Phone

+98 54 3329 5715

Fax**Email**

s_risbaf@zaums.ac.ir

Web page address**Phone**

+98 935 516 7380

Fax**Email**

niloofar.qodoosi@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Niloufar Ghodousi

Position

Dentistry student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

College of dentistry , Eastern Azadegan St., Zahedan
city

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817699693

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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