

# 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