

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of adding low level laser irradiation to drug therapy in patients affected with burning mouth syndrome: A randomized clinical trial

Protocol summary

Study aim

Determining the effect of low level laser with drug therapy in patients with oral burning mouth syndrome in comparison with the control group

Design

A clinical randomized trial with a group control, with cross randomized groups, on 46 patients, used a random number table for randomization.

Settings and conduct

10 milligram Citalopram is prescribed for all patients who where diagnosed with burning mouth syndrome in the first week and increased to 20 milligram in the second week. The samples are then divided into two groups of intervention and control by using a random number table. In the intervention group, Thor DD2 low power diode laser with 810 nano meter wavelength, 0.5 watt power and continuous radiation is used. Laser irradiation is performed 3 times in a week for up to 4 sessions. the tip of the probe is square. Laser irradiation is applied in a contact method and in contact to point for 15 seconds for each area of the affected mucosa with an area of approximately 2 cm. all these procedures will be accomplished by specialist of oral medicine in laser center of Tehran university. In the control group, laser radiation will not be done.

Participants/Inclusion and exclusion criteria

Patients with a diagnosis of burning mouth syndrome who are systemically healthy and have a daily burning sensation for 4 to 6 months with constant or increased intensity during the day.

Intervention groups

Intervention group: Patients diagnosed with burning mouth syndrome are prescribed citaloperam increased from 10 milligram in the first week and to 20 milligram in the second week and then exposed to 920 nano meter diode laser for one month (12 sessions). In the control group, patients with a diagnosis of burning mouth

syndrome increased citalopram 10 milligram in the first week and to 20 milligram in the second week and were not exposed to laser radiation.

Main outcome variables

burning rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200905048623N1**

Registration date: **2020-09-21, 1399/06/31**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-21, 1399/06/31**

Update count: **0**

Registration date

2020-09-21, 1399/06/31

Registrant information

Name

Hooman Ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8804 3288

Email address

h.ebrahimi@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of adding low level laser irradiation to drug therapy in patients affected with burning mouth syndrome: A randomized clinical trial

Public title

Evaluation of the effect of adding low level laser irradiation to drug therapy in patients affected with burning mouth syndrome: A randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients are diagnosed with burning mouth syndrome. Patients are systemically healthy. Patients with normal oral mucosa should be examined clinically. Patients have a burning sensation daily 4 to 6 months with constant or increased intensity during the day.

Exclusion criteria:

Patients with systemic problems manifested by burning mouth, such as diabetes, severe anemia, vitamin deficiency. There are contraindications to laser administration such as pregnancy, epilepsy, cancer, chemotherapy. Patients with severe psychiatric disorders, such as major depression

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomized, individual unit Using a table of random numbers, no concealment.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

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

Ethics committee of Islamic Azad university; Tehran dental branch

Street address

unit9, No9, Golestan st, Agha alikhani st, south shirazi st, vanak sq

City

Tehran

Province

Tehran

Postal code

1436936499

Approval date

2019-12-01, 1398/09/10

Ethics committee reference number

IR.IAU.DENTAL.REC.1398.047

Health conditions studied**1****Description of health condition studied**

Burning mouth syndrome

ICD-10 code

K13.7

ICD-10 code description

Other and unspecified lesions of oral mucosa

Primary outcomes**1****Description**

The amount of mouth burning is measured by asking the patient using a 0 to 10 graduated ruler.

Timepoint

The severity of burning will be measured before the start of treatment and at the end of each week after treatment (first week, second week, third week, fourth week) and the end of the third month.

Method of measurement

Patient questions are measured using the Visual Analogue Scale, a scale from 0 to 10

Secondary outcomes

empty

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

Intervention group 1: The drug given to all patients is citalopram, the initial dose of which is 10 mg and after one week it is increased to 20 mg and used once a day for one month and in half of the patients, after one week

from the start of drug treatment, laser treatment will be performed. In the intervention group, low power Thor DD2 (control unit,Thor,London,UK) diode laser with 810 nano meters wavelength and 0.5 watt power and continuous radiation is used about 15 seconds for each area were affected. The laser is performed about 3 times in a week for up to 4 sessions. The diameter of the probe tip is 1 centimeter (cm), the cross-sectional area is 0.785 cm² and the energy density is 9.5 joules / cm².

Category

Treatment - Devices

2

Description

Control group: The drug was given to all patients with citalopram (Sobhan Daru, Iran) whose initial dose was increased to 10 milligrams and after a week to 20 milligrams and used once a day for one month and half of Patients who do not receive laser treatment are in the control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad university, Tehran Dental branch

Full name of responsible person

Hooman Ebrahimi

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unit9, No9, Golestan st, Agha alikhani st, south shirazi st, vanak sq

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Hooman Ebrahimi

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available