

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the efficacy of clonazepam oral paste on pain of burning mouth syndrome

Protocol summary

Study aim

Evaluation of the efficacy of clonazepam oral paste on pain of burning mouth syndrome

Design

The total sample size is 24 patients. 12 participants in the evaluation group and 12 participants in the control group will be enrolled. Patients with recurrent aphthous stomatitis will be divided randomly (block randomization) into 2 experimental and control groups. In experimental and control groups patients will receive clonazepam oral paste and clonazepam tab 0.5 mg respectively, three times a day for 30 days.

Settings and conduct

This study is double blinded. The outcome assessor and data analyser will be blind to the type of prescribed treatment. The patients who will be referred to Shiraz Dental School for their recurrent aphthous stomatitis will be enrolled.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patients with primary BMS whose disease have been confirmed by a specialist
Exclusion criteria: The patients with primary BMS who have been under treatment for BMS during previous month
The patients who have taken anxiolytics, antidepressant or any other similar medications

Intervention groups

Intervention group: The patients will receive clonazepam oral paste 3 times daily. Control group: The patients will be prescribed 0.5 mg clonazepam tab in order to suck the tab for 5 minutes and spit out the remaining tab 3 times daily.

Main outcome variables

The amount of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120101008585N13**

Registration date: **2022-02-26, 1400/12/07**

Registration timing: **prospective**

Last update: **2022-02-26, 1400/12/07**

Update count: **0**

Registration date

2022-02-26, 1400/12/07

Registrant information

Name

Fatemeh Lavaee

Name of organization / entity

Shiraz Dental School

Country

Iran (Islamic Republic of)

Phone

+98 71 1631 9309

Email address

lavaeef@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2023-03-06, 1401/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of clonazepam oral paste on pain of burning mouth syndrome

Public title

Evaluation of the efficacy of clonazepam oral paste on pain of burning mouth syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patients with primary BMS whose disease have been confirmed by a specialist

Exclusion criteria:

The patients with primary BMS who have been under treatment for BMS during previous month The patients who have taken anxiolytics, antidepressant or any other similar medications

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Each block with 4 allocations, consisting of 2 allocations for intervention and 2 for the control group were considered. Six possible sequences of treatment allocation in each block were listed and each one was written on a card. Each time a block had been selected and the sequence of treatments was registered until the treatment allocations become completed for all 24 patients (6 blocks).

Blinding (investigator's opinion)

Double blinded

Blinding description

Treatment prescription will be done by a researcher, but pain analysis will be done by another researcher and he will be blind to the type of prescribed treatment. Also the data analyser will be blind to the type of prescribed treatment

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical

Sciences

Street address

Ghasrdasht

City

Shiraz

Province

Fars

Postal code

7195845379

Approval date

2020-07-26, 1399/05/05

Ethics committee reference number

IR.SUMS.DENTAL.REC.1399.095

Health conditions studied

1

Description of health condition studied

Burning mouth syndrome

ICD-10 code

T28.0XXS

ICD-10 code description

Burn of mouth and pharynx, sequela

Primary outcomes

1

Description

The amount of pain

Timepoint

Day 0,7,14,21,30

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patients will receive clonazepam oral paste three times a day for 30days.

Category

Treatment - Drugs

2

Description

Control group: The patients will receive clonazepam tab 0.5 mg and suck it for 5 minutes three times a day for 30days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Dental School

Full name of responsible person

Fatemeh Lavaee

Street address

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City

Shiraz

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Email

lavaeef@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Rezaianzade

Street address

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Shiraz

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7195845379

Phone

+98 71 3212 2438

Email

lavaeef@sums.ac.ir

Grant name**Grant code / Reference number**

20796

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

No

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Lavaee

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Lavaee

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Lavaee

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Statistical analysis file

When the data will become available and for how long

The data will be given to the requester by email.

To whom data/document is available

The data will be given to the requester by email

Under which criteria data/document could be used

The data will be given to the requester by email.

From where data/document is obtainable

The data will be given to the requester by email.

What processes are involved for a request to access data/document

The data will be given to the requester by email.

Comments