# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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 30days.

**Settings and conduct**
llThis 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 ۰.5 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 anloge 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**
Ghasrdasht
**City**
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**Province**
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7195845379
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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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**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**

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Associate professor
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## Person responsible for updating data

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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**