

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effectiveness of clonazepam mouthwash and the combined treatment of clonazepam mouthwash, vitamin B1 and alphalipoic acid supplements on burning of mouth in patients with idiopathic burning mouth

#### Protocol summary

##### Study aim

Determining the effect of combined treatment of clonazepam mouthwash and vitamin B1 and alphalipoic acid supplement in patients with burning mouth in people referred to the Faculty of Dentistry and affiliated hospitals of Tehran Islamic Azad University of Medical Sciences and Faculty of Dentistry of Shahid Beheshti University in the academic year 2023-2024

##### Design

The clinical trial has a control group, with parallel groups, single blind, randomized, phase 3 on 54 patients, on 2 groups, each group includes 27 patients, rand function of Excel software was used for randomization.

##### Settings and conduct

The place of study: hospitals affiliated to Tehran Islamic Azad University of Medical Sciences and Faculty of Dentistry, Shahid Beheshti University of Medical Sciences. Study population: Patients with mouth burning (54 samples); Type of blinding: double blind in the form of identical packages which have meaningful codes for the statistical consultant and the researcher is unaware of the type of treatment provided and the patients are unaware of the type of treatment received.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with healthy systemic conditions; having burning sensation in the mouth for more than 2 hours a day in 50% of the day and night hours and for a period of more than 3 months. Non-inclusion criteria: the presence of any clinical lesions of the pharynx and nose, any type of local or systemic factor, use of chemical drugs, hypersensitivity reactions, complete dental prosthesis, bad oral habits such as teeth grinding, mucosal diseases mouth such as lichen planus, benign migratory glossitis and bacterial, fungal and viral infections

##### Intervention groups

Intervention group: Clonazepam mouthwash; Control group: clonazepam mouthwash, vitamin B1 supplement and alpha lipoic acid

##### Main outcome variables

The amount of mouth burning

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230413057893N1**

Registration date: **2023-05-31, 1402/03/10**

Registration timing: **prospective**

Last update: **2023-05-31, 1402/03/10**

Update count: **0**

##### Registration date

2023-05-31, 1402/03/10

##### Registrant information

##### Name

Ali Moghadasi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4407 4766

##### Email address

am.alimoghadasi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-22, 1402/04/01

**Expected recruitment end date**

2023-12-21, 1402/09/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effectiveness of clonazepam mouthwash and the combined treatment of clonazepam mouthwash, vitamin B1 and alphasalicylic acid supplements on burning of mouth in patients with idiopathic burning mouth

**Public title**

Efficiency of combined treatment of clonazepam mouthwash and vitamin B1 and alphasalicylic acid supplements in the treatment of idiopathic burning mouth

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with healthy systemic conditions Patients who feel oral burning more than 2 hours a day in 50% of the day and night and more than 3 months.

**Exclusion criteria:**

The presence of any lesions of the pharynx and nose from a clinical point of view the use of chemical drugs hypersensitivity reactions physical or chemical factors complete dental prosthesis bad oral habits such as teeth grinding oral mucosa disease such as lichen planus benign migratory glossitis bacterial, fungal and viral infections Dry mouth primary or secondary to salivary gland disorders or after radiation therapy neurological problems endocrine disorders digestive diseases malnutrition Pregnancy/lactation sensitivity to clonazepam

**Age**

From **16 years** old to **89 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **54**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization method is done using random blocks of size 4. In these random blocks of 4, 2 samples are treated with clonazepam mouthwash alone and 2 samples are treated with clonazepam mouthwash and vitamin B1 and alpha lipoic acid supplements. The randomization process is done by Excel software. The type of treatment that the patient will receive is placed in envelopes numbered from 1 to 54 (according to the

number of samples). In this way, from the first 4 patients, 2 patients will be treated with mouthwash alone and 2 patients will be treated with mouthwash and their supplements. This process is done by the statistics consultant and they will not open the envelopes until the treatment process starts.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The drug and placebo are divided into the same packages with specific and meaningful codes for the statistical consultant, and the researcher and the patient are not aware of the type of drug in each package.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Department of Dentistry, Tehran Azad University

**Street address**

No. 9, Nistan 9th, Pasdaran Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1946853314

**Approval date**

2023-04-10, 1402/01/21

**Ethics committee reference number**

IR.IAU.DENTAL.REC.1402.001

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

Idiopathic burning mouth

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

The degree of mouth burning

**Timepoint**

Day zero, fourteen and twenty eight

**Method of measurement**

visual analogue scaling

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: These patients are given mouthwash containing clonazepam 0.5 mg/1 cc and are asked to gargle and spit 5 cc after each meal for 2-4 minutes, 3 times a day for 28 days.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Patients are given and asked for mouthwash containing clonazepam 0.5 mg/1 cc. After each meal, gargle and spit 5 cc of this medicine for 2-4 minutes for 3 times a day. In addition, vitamin B1 tablets (300 mg) twice a day and alpha lipoic acid tablets 200 mg three times a day are prescribed for them to take for 28 days.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Homa Mirzaei Roudposhti

##### Street address

Shahid Shahriari square; Evin

##### City

Tehran

##### Province

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##### Postal code

1983969411

##### Phone

+98 21 29901

##### Fax

+98 21 2243 1607

##### Email

pr-office@sbu.ac.ir

##### Web page address

<https://www.sbu.ac.ir/>

### 2

#### Recruitment center

##### Name of recruitment center

Department of Dentistry; Islamic Azad University of

Tehran

##### Full name of responsible person

Ali Moghadasi

##### Street address

No. 9, Nistan 9th; Pasdaran St.

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arezoo.alaaee@yahoo.com

##### Web page address

<https://tms.iau.ir/dental/fa>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Arash Azizi

##### Street address

No. 9, Nistan 9th; Pasdaran St.

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##### Province

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##### Postal code

1946853314

##### Phone

+98 21 2256 4571

##### Email

drarashazizi@yahoo.com

#### 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

Private

#### 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**  
Ali Moghadasi  
**Position**  
collegian  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Dentistry  
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No 4, Shahed Street  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Ali Moghadasi  
**Position**  
Student ( collegian )

**Latest degree**  
A Level or less  
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**Email**  
am.alimoghadasi@yahoo.com

## 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

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

### Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

### When the data will become available and for how long

The access period starts 6 months after the results are published

### To whom data/document is available

Researchers working in academic and scientific institutions and people who are also engaged in industry

### Under which criteria data/document could be used

They are allowed to use documents only if they use references.

### From where data/document is obtainable

Ali Moghadasi; 09190903027; Department of Oral and Dental Diseases; Department of Dentistry; Tehran  
Islamic Azad University

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

Submitting the request and clarifying the purpose of the request. If approved, the information will be provided to the applicant

### Comments