Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 alphalipoic 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 alphalipoic 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
Tehran
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.
City
Tehran
Province
Tehran
Postal code
1946853314
Phone
+98 21 2256 4571
Email
arezoo.alaee@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.
City
Tehran
Province
Tehran
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

Street address
No 4, Shahed Street

City
Tehran

Province
Tehran

Postal code
1473685686

Phone
+98 21 4407 4766

Email
am.alimoghadasi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Ali Moghadasi

Position
Student (collegian)

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

Street address
Unit 4; No 4; Shahed street; East Payambar; Ashrafi Esfahani Blvd

City
Tehran

Province
Tehran

Postal code
1473685686

Phone
+98 21 4407 4766

Fax

Email
am.alimoghadasi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Ali Moghadasi

Position
Student (collegian)

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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Unit 4; No 4; Shahed street; East Payambar; Ashrafi Esfahani Blvd

City
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Phone
+98 21 4407 4766

Fax

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