

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The Effect of Capsaicin Oral Solution in The Treatment of Burning Mouth in Patients Attending School of Dentistry and Affiliated Hospitals of Tehran Islamic Azad University of Medical Sciences

Protocol summary

Study aim

Determining the effect of Capsaicin and placebo oral solution in patients with burning mouth in patients referred to the School of Dentistry and affiliated hospitals of Tehran Islamic Azad University of Medical Sciences in the academic year 2022-2023

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2-3 on 22 patients. Excel software rand function was used for randomization

Settings and conduct

School of Dentistry and Affiliated Hospitals of Tehran Islamic Azad University, Blinding patient and outcome assessor, Coding oral solutions by a person outside the research team, Fill in forms 1, 2 and 3 on day 0, fill in forms 4 and 5 on day 30, measure non-stimulating saliva

Participants/Inclusion and exclusion criteria

Inclusion criteria: existence of daily sensation of bilateral burning in the mouth continuously (4 to 6 months) and without the appearance of specific clinical symptoms, improvement of oral burning symptoms by eating food or drinking water; non-interference of burning mouth with the patient's sleep. Exclusion criteria: presence of any throat and nose lesions clinically; any local or systemic disease; use of herbal or chemical drugs; hypersensitivity reactions, physical or chemical factors; complete dental prosthesis; bad oral habits such as Bruxism; oral mucosal diseases such as Lichen planus; benign migratory glossitis, and bacterial, fungal, and viral infections; neurological problems, endocrine disorders, anemia, gastrointestinal diseases, malnutrition; pregnancy or lactation, and allergies to peppers.

Intervention groups

Intervention group: 11 eligible volunteers with burning mouth between 30 and 80 years old referred to the School of Dentistry of Tehran Islamic Azad University of Medical Sciences who have completed the voluntary

consent form. Intervention: Capsaicin oral solution

Main outcome variables

Improvement of burning mouth

General information

Reason for update

Acronym

VAS

IRCT registration information

IRCT registration number: **IRCT20220117053748N1**

Registration date: **2022-02-01, 1400/11/12**

Registration timing: **prospective**

Last update: **2022-02-01, 1400/11/12**

Update count: **0**

Registration date

2022-02-01, 1400/11/12

Registrant information

Name

Kimia Ghods

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2269 2735

Email address

kimiaghods2@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-09, 1400/11/20

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Capsaicin Oral Solution in The Treatment of Burning Mouth in Patients Attending School of Dentistry and Affiliated Hospitals of Tehran Islamic Azad University of Medical Sciences

Public title
The Effect of Capsaicin on Burning Mouth

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Absence of systemic disease Existence of daily sensation of bilateral burning mouth continuously (4 to 6 months) and without obvious clinical symptoms Improve the symptoms of burning mouth by eating food or drinking water Non-interference of burning mouth with the patient's sleep
Exclusion criteria:
 Existence of any throat and nose lesions clinically Existence of any local factor or systemic disease Herbal or chemical drugs consumption Existence of hypersensitivity reactions Existence of physical or chemical agents Existence of complete dentures, bad oral habits such as Bruxism, oral mucosal diseases such as lichen planus, benign migratory glossitis, and bacterial, fungal, and viral infections. Neurological problems, endocrine disorders, anemia, gastrointestinal diseases, malnutrition, pregnancy and lactation, and pepper allergy Existence of bad oral habits like Bruxism Existence of oral mucosal diseases such as Lichen planus, benign migratory glossitis, and bacterial, fungal, and viral infections Existence of neurological problems Existence of endocrine disorders Existence of anemia Existence of gastrointestinal diseases Existence of malnutrition Pregnancy and lactation Existence of pepper allergy

Age
From **30 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation of participants in the study by the group statistician to random 4 blocks will be done using the Rand option of Excel software. Then, according to the number of samples, envelopes will be prepared in the

package and given to the random person. Prior to treatment, the oral solution of capsaicin and placebo will be coded by someone outside the clinical research team. Therefore, both the patient and the evaluator will be blind.

Blinding (investigator's opinion)

Double blinded

Blinding description

Prior to treatment, the oral solution of capsaicin and placebo will be coded by someone outside the clinical research team. Therefore, both the participants in the study and the outcome evaluator will be blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Islamic Azad University - Dental Branch Tehran - Iran

Street address

No. 9, 9th Neystan Street, Pasdaran Street

City

Tehran

Province

Tehran

Postal code

1931843511

Approval date

2022-01-10, 1400/10/20

Ethics committee reference number

IR.IAU.DENTAL.REC.1400.155

Health conditions studied

1

Description of health condition studied

Burning mouth

ICD-10 code

T28.0

ICD-10 code description

Burn of mouth and pharynx

2

Description of health condition studied

Dry mouth

ICD-10 code

R68.2

ICD-10 code description

Dry mouth, unspecified

Primary outcomes

1

Description

Burning score in the standard burning mouth questionnaire

Timepoint

Filling in the mouth burning questionnaire at the beginning of the study (before the intervention) and on days 0 and 30 after starting the capsaicin solution

Method of measurement

Standard burning mouth questionnaire

Secondary outcomes

1

Description

Amount of Xerostomia

Timepoint

At the beginning of the study (before the intervention) and day 0, 30 after the start of capsaicin solution

Method of measurement

Standard dry mouth questionnaire

Intervention groups

1

Description

Intervention group: Capsaicin oral solution using 10% extract of a mixture of coriander (*Coriandrum sativum* L.) and *Hypericum perforatum* (*Hypericum perforatum* L.) which was prepared by accelerated solvent method and 0.25% of Capsaicin in hydroalcoholic base with liquid fructose solution and polyethylene glycol are formulated and standardized based on the presence of Capsaicin. This solution is diluted 20 drops of medicine or placebo in 20 cc of water three times a day for 30 days and gargle for at least 2 minutes.

Category

Treatment - Drugs

2

Description

Control group: This oral solution has been formulated using permitted pharmaceutical food dyes based on hydroalcoholic as well as liquid fructose solution and PEG, but without the use of coriander fruit extract, *Hypericum perforatum* and Capsaicin. This solution is diluted 20 drops of medicine or placebo in 20 cc of water three times a day and gargle for at least 2 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry and Affiliated Hospitals, Islamic Azad University of Tehran Medical Sciences

Full name of responsible person

Kimia Ghods

Street address

No. 9, 9th Neystan Street, Pasdaran Street

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1946853314

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alae.a@iautmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arezo Alae

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No. 9, 9th Neystan, Pasdaran St.

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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

kimiaghods2@gmail.com

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Kimia Ghods

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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