

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the Effectiveness Of Melatonin in patients with Burning Mouth syndrome

Protocol summary

Study aim

Treatment effect of Melatonin on Burning Mouth Syndrome

Design

Sample size 15 patients in each group randomization: simple clinical trial: phase 2 or 1

Settings and conduct

Patients with Burnin Mouth Syndrome and inclusion criteria will be divided into two groups randomly and evaluated for 24 Weeks. Melatonin will be provided, patients and data analyzers will be blind to groups of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: burning mouth at all times; lack of systemic disease and chronic medication; patients over 18 years of age; use of smoking; no oral lesion. Exclusion criteria: elderly people with glaucoma; those who take aspirin or heparin or warfarin; those who take acetone and metoprolol because they reduce the effect of melatonin; epilepsy.

Intervention groups

Melatonin group Placebo group

Main outcome variables

Improvement burning and sleep disorders

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141220020377N3**

Registration date: **2019-08-14, 1398/05/23**

Registration timing: **prospective**

Last update: **2019-08-14, 1398/05/23**

Update count: **0**

Registration date

2019-08-14, 1398/05/23

Registrant information

Name

Tahereh Nosratzahi

Name of organization / entity

Dental School of Zahedan University

Country

Iran (Islamic Republic of)

Phone

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nosratzahi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness Of Melatonin in patients with Burning Mouth syndrome

Public title

Melatonin in patients with Burning Mouth syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Burning mouth at all times Lack of Systemic Disease and chronic medication Patients over 18 years of age No use of Smoking Lack of oral lesion

Exclusion criteria:

Elderly people with glaucoma Those who take aspirin or

heparin or warfarin Those who take acetone and metoprolol because they reduce the effect of melatonin
Patients with epilepsy

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized Stratified Blocking In this study, patients are randomly divided into two groups. Randomization is performed Based on the random numbers table obtained from www.randomizer.org. Even number will be allocated in intervention group and odd number in control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are examined by a dentistry student who is blind to the drug before treatment and VAS (Visual Analog Scale) is evaluated.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University Of Medical Science

Street address

Oral Medicine Department, Faculty Of Dentistry,
Azadegan Street, Zahedan, Iran

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817699693

Approval date

2019-05-26, 1398/03/05

Ethics committee reference number

IR.ZAUMS.REC.1398.157

Health conditions studied

1

Description of health condition studied

Burning Mouth Syndrome

ICD-10 code

T28.5

ICD-10 code description

Burning Mouth Syndrome

Primary outcomes

1

Description

Level of Sensation

Timepoint

The First Visit, 8 weeks Later, 4 weeks Later, 4 weeks Later, 8 weeks Later

Method of measurement

Visual Analogue Scale

2

Description

Average sleep disorder

Timepoint

The First Visit, 24 weeks Later

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In intervention group patients will use Melatonin Tab 3 Mg (Iran Construction of A-IHavi Company) 4 times a day for 5 month.

Category

Treatment - Drugs

2

Description

Control group: In Control group patients will use PlaceboTab 4 times a day for 5 month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral medicine Department, Faculty Of Dentistry

Full name of responsible person

Dr.Tahereh Nosratzehi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Mohsen Taheri

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Grant name

Vice chancellor for research, Zahedan University of
Medical Sciences

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Dr.Tahereh Nosratzehi

Position

Associated Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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

No - There is not 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

No- There is no plan to make this available at the present time

When the data will become available and for how long

starting 10 months after publication

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

It is permitted to use the data in other studies with reference.

From where data/document is obtainable

Nosratzehi@zaums.ac.ir

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

Sending email to authors

Comments