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. Exclusin criteria: elderly people with glaucoma; those who take aspirin or heparin or warfarin; those who take acetonol 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 Nosratzehi
Name of organization / entity
Dental School of Zahedan University
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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 acetonol 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

Randomizd 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-lHavi 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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Email
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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
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What processes are involved for a request to access data/document
Sending email to authors
Comments