Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effectiveness Of Melatonin in patients with Atypical Facial Pain

Protocol summary

Study aim
Treatment effect of Melatonin on Atypical Facial Pain
Design
En Sample size 15 patients in each group randomization: simple clinical trial: phase 2 or 1
Settings and conduct
En Patients with Atypical Facial Pain 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
En Inclusion criteria: Pian 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 Pain and sleep disorders

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20141220020377N4**
Registration date: **2019-08-17, 1398/05/26**
Registration timing: **prospective**

Last update: **2019-08-17, 1398/05/26**
Update count: **0**
Registration date
2019-08-17, 1398/05/26

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 Atypical Facial Pain

Public title
Melatonin in patients with Atypical Facial Pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pain 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 atenolol and

metoprolol because they reduce the effect of melatonin
Patients with epilepsy

Age
From **18 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Care provider
- 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

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Zahedan

Province
Sistan-va-Balouchestan

Postal code
9817699693

Approval date
2019-08-07, 1398/05/16

Ethics committee reference number
IR.ZAUMS.REC.1398.203

Health conditions studied

1

Description of health condition studied
Atypical Facial Pain

ICD-10 code
G50.1

ICD-10 code description
Atypical facial pain

Primary outcomes

1

Description
Level of Pain

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: 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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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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Person responsible for updating data

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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