Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of melatonin combined with betamethasone mouthwash compared to betamethasone mouthwash alone in the treatment of ulcerative oral lichen planus

Protocol summary

Study aim
Investigating the effect of melatonin combined with betamethasone mouthwash compared to betamethasone mouthwash alone in the treatment of ulcerative oral lichen planus

Design
controlled clinical trial, phase 3, with two-parallel groups, triple -blind

Settings and conduct
This study will be conducted in Tabriz Dental Faculty. The random assignment sequence will be determined by a person not involved in the study using G-Power software. To hide the allocation of drugs, they will be placed in opaque envelopes, numbered consecutively. Eligible people will be placed in two intervention and control groups using the random block method with a block size of 4 and with a 1:1 allocation sequence.

Participants/Inclusion and exclusion criteria
Entry criteria include: diagnosis of oral lichen planus using clinical criteria and histopathology confirmation, age range 18 to 70 years; Exclusion criteria include: pregnancy and breastfeeding, use of immunosuppressive drugs

Intervention groups
Intervention group: Intervention group: Mg aluminum mouthwash and betamethasone 3 times, 5 cc each time, and 5 mg melatonin tablet 1 tablet two hours before bedtime for 9 weeks. Control group: Control group: Mg aluminum mouthwash and betamethasone 3 times, 5 cc each time and a placebo containing (starch and magnesium stearate) 1 piece a day two hours before going to sleep will be used for 9 weeks

Main outcome variables
Pain intensity, lesion size, Thongprasom scale

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230823059238N2**
Registration date: **2023-12-23, 1402/10/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-23, 1402/10/02**
Update count: **0**

Registration date
2023-12-23, 1402/10/02

Registrant information
Name
Parya Emamverdizadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 41 3335 5965
Email address
emamverdizdeh@tbzmed.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-12-11, 1402/09/20
Expected recruitment end date
2024-05-30, 1403/03/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of melatonin combined with betamethasone mouthwash compared to betamethasone mouthwash alone in the treatment of ulcerative oral lichen planus

Public title
Investigating the effect of melatonin combined with betamethasone mouthwash compared to betamethasone mouthwash alone in the treatment of ulcerative oral lichen planus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive diagnosis of ulcerative oral lichen planus based on clinical findings: white and red components with different designs, presence of reticular or papular tissue with erogenous lesions and histopathological criteria: 1) hyperparakeratosis or hyperorthokeratosis areas, often with thickening of the granular cell layer and a saw-tooth appearance in Rat pegs 2) Condensed degeneration or necrosis in the basal cell layer 3) An eosinophilic band that may be seen just below the basement membrane and contains fibrin covering the lamina propria. 4) Dense subepithelial band-like infiltration of lymphocytes and macrophages 5- Presence Ulcer or fibrinopurulent membrane Patients with complete records including demographic and clinical information Patients without underlying disease People who have the ability to give informed consent and do not need a legal representative.

Exclusion criteria:
pregnant women People with underlying disease Any treatment that has been done for these injuries Use of immunosuppressive drugs Incomplete file The patient's unwillingness to participate in the research

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants will be placed in two intervention and control groups using a random block method with a block size of 4 and with a 1:1 allocation sequence. The allocation sequence will be determined by a person not involved in the study using G-Power software, placed in consecutively numbered opaque envelopes to conceal drug or placebo allocation, and prepared according to the allocation sequence. It will be done by a person not involved in the research from number 1 to 32.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Medicines will be packed in two separate envelopes in a completely similar way in terms of shape and color. The person selecting the research subjects, participants, researchers and data analysts will be unaware of the type of intervention received.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Science

Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Approval date
2023-10-16, 1402/07/24

Ethics committee reference number
IR.TBZMED.REC.1402.564

Health conditions studied

1

Description of health condition studied
Oral lichen planus

ICD-10 code
L43.8

ICD-10 code description
Other lichen planus

Primary outcomes

1

Description
severity of pain

Timepoint
Before starting the intervention, 4 and 9 weeks after the intervention

Method of measurement

The severity of pain will be evaluated through visual analogue scale (VAS)

2

Description
The size of the lesions
Timepoint
Before starting the intervention, 4 and 9 weeks after the intervention
Method of measurement
The size of the lesions will be measured with the help of gauze paper.

3

Description
Appearance of lesions
Timepoint
Before starting the intervention, 4 and 9 weeks after the intervention
Method of measurement
The appearance of lesions will be measured by Thongprasom scale and includes 6 grades: zero = perfectly healthy, 1 = mild white lines without inflammatory regions, 2 = white lines with atrophic regions smaller than 1 cm2, 3 = white lines with atrophic regions larger than 1 cm2, 4 = white lines accompanied with erosive regions less than 1 cm2, 5 = white lines with erosive areas larger than 1 cm2

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Mg aluminum mouthwash and betamethasone 3 times, 5 cc each time, and 5 mg melatonin tablet 1 tablet two hours before bedtime for 9 weeks.
Category
Treatment - Drugs

2

Description
Control group: Control group: Mg aluminum mouthwash and betamethasone 3 times, 5 cc each time and a placebo containing (starch and magnesium stearate) 1 piece a day two hours before going to sleep will be used for 9 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental faculty at Tabriz university of medical sciences
Full name of responsible person
Parya Emamverdizadeh
Street address
Tabriz University of Medical Sciences, Dental faculty, Golgasht Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 41 3335 5965
Email
emamverdizadeh@bzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Parviz Shahabi
Street address
Research department, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Phone
+98 41 3335 5921
Email
dabirkhanecent@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Yousef Navidpour

Position
Dental Student

Latest degree
Bachelor

Other areas of specialty/work
Dentistry

Street address
Tabriz University of Medical Sciences, Dental Faculty, Golgasht Street, Tabriz.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3335 5965

Email
Yousefnavidpour@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Parya Amvardizadeh

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Tabriz University of Medical Sciences, Dental faculty, Golgasht Street, Tabriz.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3335 5965

Email
emamverdizadeh@bzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Yousefnavidpour

Position
Dental Student

Latest degree
Bachelor

Other areas of specialty/work
Dentistry

Street address
Tabriz University of Medical Sciences, Dental Faculty, Golgasht Street, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3335 5965

Email
Yousefnavidpour@gmail.com

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