

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

emamverdizadeh@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 cm<sup>2</sup>, 3 = white lines with atrophic regions larger than 1 cm<sup>2</sup>, 4 = white lines accompanied with erosive regions less than 1 cm<sup>2</sup>, 5 = white lines with erosive areas larger than 1 cm<sup>2</sup>

## **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, Goltasht Street, Tabriz

##### **City**

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##### **Province**

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##### **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, Goltasht Street, Tabriz

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##### **Phone**

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##### **Email**

dabir Khanecent@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

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

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## 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

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## 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

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**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