

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)

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Email address

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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

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Tabriz University of Medical Sciences, Dental faculty, Goltasht Street, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Parviz Shahabi

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Research department, central construction number 2, Tabriz University of Medical Sciences, Goltasht Street, Tabriz

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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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Parya Amvardizadeh

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Latest degree

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Person responsible for updating data

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Position

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Latest degree

Bachelor

Other areas of specialty/work

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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