

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effectiveness of melatonin-containing mucoadhesive on minor recurrent aphthous stomatitis

Protocol summary

Study aim

Determination of the effectiveness of melatonin-containing mucoadhesive on minor recurrent aphthous stomatitis

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 44 patients. Random allocation software 2 for randomization.

Settings and conduct

Toouba Dental Clinic, Mazandaran University of Medical Sciences How to intervene in the intervention group (with melatonin mucosal adhesive) and control (placebo): Mucosal adhesive 3 times a day (Morning, afternoon and night) for 30 minutes and removing then (In addition to the examination on the day of visit), the patient should revisit on the third, fifth, and seventh days to have the pain level with the Visual analogue scale, the size of the ulcer with the probe, as well as the length of the healing period In this double-blind study (researcher, analyst and participant) for blinding, codes A (melatonin) and B (placebo) will be generated using software. Finally, the codes will be placed in a sealed envelope and the sample number will be written on the envelope. These envelopes, along with the mucosal adhesive, will be in dark packaging with the same color and shape.

Participants/Inclusion and exclusion criteria

Inclusion: Men and women aged 18 to 50 years, with aphthous lesions (up to 48 hours from the formation of the lesion, with a size less than 10 mm and a diameter greater than 2 mm), lesions of the lips and buccal mucosa Exclusion: pregnancy or lactation, ulcers as a manifestation of a systemic disease, use of non-steroidal anti-inflammatories, opioids, immunomodulatory agents, and analgesics

Intervention groups

3 pieces of mucosal adhesive will be glued daily (a total of 21), use for 30 minutes (without eating or drinking at the time of use) and removing then by patient

Main outcome variables

pain; size of the lesion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240712062408N1**

Registration date: **2024-12-06, 1403/09/16**

Registration timing: **prospective**

Last update: **2024-12-06, 1403/09/16**

Update count: **0**

Registration date

2024-12-06, 1403/09/16

Registrant information

Name

Pouria Jahanbani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 936 823 7147

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-10, 1403/09/20

Expected recruitment end date

2025-03-10, 1403/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of melatonin-containing mucoadhesive on minor recurrent aphthous stomatitis

Public title

The effect of melatonin on aphthous ulcers

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Men and women aged 18 to 50 years who have the ability to follow the doctor's recommendations who are willing to participate in the study and do not use painkillers during it who have a Aphthous ulcer (no more than 48 hours have passed since the lesion formed;) with a size smaller than 10 mm and a diameter greater than 2 mm patients who have Aphthous ulcer in the lips and buccal mucosa (due to greater availability and fewer movements, which allow the mucosal adhesive to remain on the lesion)

Exclusion criteria:

Due to insufficient information on drug interactions of melatonin, individuals using other medications should also be excluded from the study Pregnancy or lactation Ulcer as a manifestation of a systemic disease such as Behçet's disease, ulcerative colitis, Crohn's disease, or acquired immunodeficiency Use of nonsteroidal anti-inflammatory drugs, narcotics, immunomodulating agents, systemic antibiotics within 2 weeks prior to study entry Treatment with any oral topical medication within 1 month prior to study entry Invasive dental procedure within 2 weeks prior to study entry Patient using toothpaste containing anti-inflammatory drugs Individuals working night shifts should also be excluded due to the possible drowsiness effects of melatonin Use of sedatives

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to allocate the samples to two groups, the random block method will be used. For this purpose, patients will receive numbers 1 to 44. The randomization unit will be individually and according to the number with blocks of 2 people. The selection of the type of group for each person will be done through random allocation 2

statistical software. Using the software, codes A and B will be generated. Finally, the codes will be placed in a sealed envelope and the sample number will be written on the envelope. After the arrival of each sample, the doctor will test the desired drug, which is placed in dark packages with the same color and shape and is supplied with each envelope on the patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blind (i.e., the patient, the data collector (researcher, clinical caregiver and outcome assessor), and the person conducting the statistical analysis are unaware of and blind to the intervention). These people will not know how to distribute the adhesives, and the adhesives will be available to patients in dark packages with the same color and shape.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

Street address

Moallem Square, Vice Chancellor for Research and Technology of Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

4817844718

Approval date

2024-10-01, 1403/07/10

Ethics committee reference number

IR.MAZUMS.REC.1403.300

Health conditions studied**1****Description of health condition studied**

minor recurrent aphthous stomatitis

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

The distance between the 2 outer edges of the ulcer border in mm; lesions less than 1 mm in diameter will be considered healed.

Timepoint

The day of referral (starting the use of the drug), the third, fifth and seventh day after that

Method of measurement

To determine the wound size, the researcher measures the distance between the 2 outer edges of the wound border in millimeters using a calibrated dental probe (D&G, Pakistan)

2

Description

Patients are taught to determine the intensity of their pain based on a visual analogue scale. Patients will record their pain in a checklist 3 times a day after each meal and lesions with a pain value of 1 cm or less will be considered healed.

Timepoint

3 times a day until the lesion heals

Method of measurement

Using a visual analogue scale, so that the patient marks his pain level from 0 to 10 3 times a day after each meal on a 10 cm line.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Use of mucosal adhesive containing melatonin; Chemical composition: Avicel® (20mg), Magnesium stearate (2.5mg), Corn starch (7mg), D-mannitol (40mg), Aerosil® 200 (0.5mg), Carbopol 974p (5mg), Polyethylene glycol 6000 (10mg), Melatonin (15mg); Dose: 45 mg of melatonin per day, one 15 mg muco-adhesive each time (3 times); Duration of use: until the lesion heals (maximum 7 days).

Category

Treatment - Drugs

2

Description

Control group: placebo; The chemical composition and method of use will be similar to the main medication but without melatonin.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Touba dental clinic

Full name of responsible person

Pouria Jahanbani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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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

Mazandaran 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

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Contact

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Person responsible for updating data

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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