Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
p.jkenari@gmail.com

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 mucusal 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: plasebo; 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
Street address
Khazar Blvd., Touba dental clinic
City
Sari
Province
Mazandaran
Postal code
4816895475
Phone
+98 11 3340 5474
Email
p.jkenari@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Azam Haddadi
Street address
Khazar Blvd., Touba dental clinic
City
Sari
Province
Mazandaran
Postal code
4816895475
Phone
+98 11 3340 5474
Email
p.jkenari@gmail.com
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

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Pouria Jahanbani

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

Street address
Khazar Blvd., Touba dental clinic

City
Sari

Province
Mazandaran

Postal code
4816895475

Phone
+98 11 3340 5474

Email
p.jkenari@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Pouria Jahanbani

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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City
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Province
Mazandaran

Postal code
4816895475

Phone
+98 11 3340 5474

Email
p.jkenari@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Pouria Jahanbani

Position
Student

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A Level or less

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Province
Mazandaran

Postal code
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Email
p.jkenari@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