Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Hesperidin mouthwash in comparison with nystatin on patients with Denture Stomatitis: A Clinical Trial

Protocol summary

Study aim

To compare the efficacy of hesperidin and nystatin mouthwashes in reducing lesion size and Candida albicans colony counts in patients with type II denture stomatitis

Design

This is a randomized, controlled, double-blind, two-arm, parallel-group Phase II clinical trial with a target sample size of 24 patients, comprising 12 patients per group. Participants will be individually assigned to receive either hesperidin or nystatin mouthwash using simple randomization generated by the RAND function in Microsoft Excel.

Settings and conduct

At Tooba Dental Clinic in Sari, consenting patients will be randomized to hesperidin or nystatin mouthwash for two weeks. Lesions will be measured with calipers and photographed weekly; palatal smears and cultures will be obtained before and after treatment. Similar containers will be dispensed by personnel other than the examiner, keeping participants, clinicians, and assessors blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Good general health, use of a removable maxillary denture, type II denture stomatitis confirmed by an oral medicine specialist. Exclusion criteria: Use of antifungals, antibiotics, or corticosteroids within the previous month; nystatin allergy; immunodeficiency; Alzheimer’s disease; psychological or masticatory muscle disorders; inability to use mouthwash; and an ill-fitting or discolored denture.

Intervention groups

Intervention group: Hesperidin mouthwash. Control group: Nystatin mouthwash at a concentration of 100,000 units/mL. Both groups will use 20 mL of the assigned mouthwash three times daily for two weeks. Patients will retain the mouthwash in their mouth for one minute per application and avoid eating or drinking for one hour afterward.

Main outcome variables

Change in denture stomatitis lesion size, assessed by lesion length and width; change in Candida colony growth in culture.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260531069588N1**
Registration date: **2026-11-04, 1405/08/13**
Registration timing: **prospective**

Last update: **2026-11-04, 1405/08/13**
Update count: **0**

Registration date

2026-11-04, 1405/08/13

Registrant information

Name
Amirali norozi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 4201 0493
Email address
amiralinorozi200@gmail.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-22, 1405/09/01

Expected recruitment end date

2027-04-04, 1406/01/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Hesperidin mouthwash in comparison with nystatin on patients with Denture Stomatitis: A Clinical Trial

Public title
Comparison of the effects of hesperidin and nystatin mouthwashes in treating mucosal inflammation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Use of a removable maxillary denture Diagnosis of type II denture stomatitis confirmed by an oral medicine specialist Good general health
Exclusion criteria:
Use of antifungal medications, antibiotics, or corticosteroids within the past month History of allergy to nystatin mouthwash Inability to use mouthwash
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization will be performed, with the individual patient as the unit of randomization. A random number between zero and one will be generated for each eligible patient using the RAND function in Microsoft Excel. Patients assigned a number below 0.5 will receive hesperidin mouthwash, whereas those assigned a number of 0.5 or above will receive nystatin mouthwash.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, treating clinicians, and examiners responsible for outcome assessment will be unaware of participants' group allocation and the mouthwash received. Hesperidin and nystatin mouthwashes will be supplied in containers with similar shape, size, and color. The mouthwashes will be dispensed by personnel other than the examiner so that the person examining and measuring the lesions remains unaware of the assigned treatment.
Placebo
Not 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
Moalem
City
Sari
Province
Mazandaran
Postal code
4815733971
Approval date
2024-02-05, 1402/11/16
Ethics committee reference number
IR.MAZUMS.REC.1402.597

Health conditions studied

1

Description of health condition studied
Denture stomatitis type II
ICD-10 code
K12
ICD-10 code description
Stomatitis and related lesions

Primary outcomes

1

Description
Width of the erythematous denture stomatitis lesion, measured in centimeters using a caliper.
Timepoint
At baseline, before starting the mouthwash, and on days 7 and 14 after the start of the intervention.
Method of measurement
Lesion width will be measured using a caliper by a specialist and recorded in centimeters.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Hesperidin mouthwash, 20 milliliters per application, three times daily for two weeks. Patients will retain the mouthwash in their mouth for one minute and avoid eating or drinking for one hour afterward.
Category
Treatment - Drugs

2

Description
Control group: Nystatin mouthwash at a concentration of 100,000 units per milliliter, 20 milliliters per application, three times daily for two weeks. Patients will retain the mouthwash in their mouth for one minute and avoid eating or drinking for one hour afterward.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tooba Dental Clinic
Full name of responsible person
Dr. Atefeh Ramzani
Street address
Tooba Dental Clinic, Khazar Boulevard, Sari, Mazandaran Province
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3324 0002
Email
research@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Ahmadali Enayati
Street address
Deputy for Research and Technology Building, Moalem Square, Sari, Mazandaran Province
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3324 0002
Email
research@mazums.ac.ir
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
Amirali Norozi
Position
PhD student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Mehmansara Payamavaran 7
City
Qaemshahr
Province
Mazandaran
Postal code
۴۸۱۵۷۳۳۹۷۱
Phone
+98 11 4201 0493
Fax
Email
amiralinorozi200@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Amirali Norozi
Position
PhD student
Latest degree
A Level or less

Other areas of specialty/work
Dentistry
Street address
Mehmansara Payamavaran 7
City
Qaemshahr
Province
Mazandaran
Postal code
۴۸۱۵۷۳۳۹۷۱
Phone
+98 11 4201 0493
Fax
Email
amiralinorozi200@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Amirali Norozi
Position
PhD student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Mehmansara Payamavaran 7
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Mazandaran
Postal code
۴۸۱۵۷۳۳۹۷۱
Phone
+98 11 4201 0493
Fax
Email
amiralinorozi200@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No further information is 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
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available