Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Therapeutic Effect of Mouthwash Containing Matricaria chamomilla Extract and Nystatin Suspension on Patients with Denture Stomatitis- a randomized clinical trial

Protocol summary

Study aim
Determining the therapeutic effect of mouthwash containing chamomile extract compared to nystatin suspension in patients with denture stomatitis

Design
A single-blind, randomized clinical trial will be conducted on 24 patients with denture stomatitis. The rand function of Excel software will be used for randomization.

Settings and conduct
The location for collecting the necessary information will be Tooba Dental Clinic. The mouthwash will be manufactured at the Faculty of Pharmacy, Mazandaran University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Healthy individuals with complete maxillary dentures and denture stomatitis (type II) will be included. Patients with a history of using antifungal drugs, antibiotics and corticosteroids in the last month, allergy to nystatin, patients with immunodeficiency, Alzheimer's, psychological disorders, chewing muscle disorder, unable to use mouthwash, and patients with loose and discolored dentures will be excluded from the study.

Intervention groups
Two groups Group 1 = receiving mouthwash containing chamomile Group 2 = receiving nystatin suspension

Main outcome variables
Erythematous lesions are examined on days 0, 7, and 14.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241231064232N1**
Registration date: **2025-02-24, 1403/12/06**
Registration timing: **registered_while_recruiting**
Last update: **2025-02-24, 1403/12/06**
Update count: **0**

Registration date
2025-02-24, 1403/12/06

Registrant information

Name
Pooya Rabiee

Name of organization / entity

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Iran (Islamic Republic of)

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+98 11 3324 4894

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pooyarabiee@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-20, 1403/11/01

Expected recruitment end date
2025-06-22, 1404/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Therapeutic Effect of Mouthwash Containing Matricaria chamomilla Extract and Nystatin Suspension on Patients with Denture Stomatitis- a randomized clinical trial

Public title
Comparing the effects of chamomilla mouthwash and nystatin in the treatment of denture stomatitis

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy individuals with maxillary complete dentures and denture stomatitis (type II)
Exclusion criteria:
Age
No age limit
Gender
Both

Phase
0
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals will be randomly assigned to two mouthwash groups (the RAND function in Excel will be used so that the values produced for each individual will be placed in the chamomile mouthwash group if less than 0.5 and in the nystatin mouthwash group if greater than 0.5).
Blinding (investigator's opinion)
Single blinded
Blinding description
The study will be single-blinded, and the only person recording changes in the groups will not be aware of the type of mouthwash.
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
moallem
City
sari
Province
Mazandaran
Postal code
4815733971
Approval date
2024-12-25, 1403/10/05
Ethics committee reference number
IR.MAZUMS.REC.1403.411

Health conditions studied

1

Description of health condition studied
denture stomatitis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
fungi load
Timepoint
day 0, 7, and 14
Method of measurement
Colony cultivation and counting

2

Description
lesion diameter
Timepoint
day 0, 7, and 14
Method of measurement
measuring with probe

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Using mouthwash containing chamomile/ Patients are asked to swish 10 cc of chamomile mouthwash in their mouth 3 times (every 8 hours) and gargle for 1 minute, then spit it out, and avoid eating or drinking for at least 1 hour after using the mouthwash. Treatment will continue for 2 weeks, and erythematous lesions will be examined on days 0, 7, and 14.
Category
Treatment - Drugs

2

Description
Intervention group: Using nystatin suspension/ Patients are asked to place 20 drops (1 mL) of nystatin suspension 100,000u/ml in the mouth, gargle for 1 minute, then spit out, and refrain from eating or drinking for at least 1 hour after using the mouthwash. Treatment will continue for 2 weeks, and erythematous lesions will be assessed on days 0, 7, and 14.
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
touba dental clinic
Full name of responsible person
دکتر محمد ابراهیمی ساروی
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
Research Center of Mazandaran University of Medical Sciences
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
Dr. Mohammad Ebrahimi Saravi
Position
Associate professor
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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