Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Investigating the effect of atorvastatin mouthwash on denture stomatitis compared to nystatin mouthwash

Protocol summary

Study aim
1- Determining the severity of denture stomatitis in patients receiving maxillary atrovastatin. 2- Determining the severity of dental stomatitis in the patients recipient of nystatin

Design
This study was performed as a clinical, triple-blind clinical trial. Patients were randomly divided into two groups using hexagonal blocks. One group received atorvastatin paste and the other group (control) received nystatin. To determine the sample size, the data were extracted from previous studies

Settings and conduct
This study was performed as a clinical, triple-blind clinical trial. These patients were divided into two groups. Visits took place on the first, seventh, and fifteenth days. The drugs delivered to patients in both groups had the same packaging. Then the drug and method of use were given to the patient. The research site was Mazandaran dental clinics.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients using dentures with stomatitis denture lesions in the palate. Conditions of non-entry: denture with poor compliance. Prohibition of prescribing atorvastatin. Prohibition of prescribing nystatin.

Intervention groups
Attrovastatine paste was delivered to patients as a tube for two weeks for the case group. Nystatin (purchased from products of Jabraban Hayan Pharmaceutical Company) was given as an ointment to patients in the control group for one week.

Main outcome variables
Lesion size decreases

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141130020158N3**
Registration date: **2022-09-03, 1401/06/12**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-03, 1401/06/12**
Update count: **0**

Registration date
2022-09-03, 1401/06/12

Registrant information

Name
Mohammad Ebrahimi Saravi

Name of organization / entity
Mazandaran University of Medical Sciences / Dentistry Faculty

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of atorvastatin mouthwash on denture stomatitis compared to nystatin mouthwash

Public title
The effect of Atorvastatin on Denture Stomatitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients using dentures with stomatitis denture lesions in the palate.
Exclusion criteria:
inability to use mouthwash Temporomandibular disorders history of using antifungals, antibiotics, corticostroids in las one month allergy to Nystatine moutwash patients with inappropriateseal and change in color Imunosupresive Alzheimer psychotic disorders
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **22**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of samples will be done using Microsoft Excel computer software. In this way, a code is assigned to each sample, and after entering the codes related to the patients in one column, using the Randbetween plugin, the codes are assigned to two equal rows (0 and 1, respectively, for the control and intervention groups) will be divided. Then, based on the codes placed in each patient, the patients will be grouped by the person who performed the randomization, and the study process will be carried out for each group according to the intervention and control.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, the statistician who was responsible for data analysis, the main researcher, and the participants were blinded. The mouthwash containers were similar, so it was not possible to distinguish the type of mouthwash for researchers and participants. The statistician (data analyst) was not present at the work site and was blinded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mazandaran University of medical science
Street address
Mazandaran University of medical science
City
Sari
Province
Mazandaran
Postal code
4816895475
Approval date
2021-09-01, 1400/06/10
Ethics committee reference number
IR.MAZUMS.REC.1400.421

Health conditions studied

1

Description of health condition studied
Denture stomatitis
ICD-10 code
K12.1
ICD-10 code description
Other forms of stomatitis

Primary outcomes

1

Description
Repair denture stomatitis
Timepoint
Day 0 and 14
Method of measurement
Length and width of the lesson

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Atorvastatin paste was delivered to patients as a tube for two weeks for the case group. The atorvastatin group placed the atorvastatin paste in the maxilla denture 4 times daily after each meal after cleaning the denture with a toothbrush, and the denture did not come out until the next meal.
Category
Treatment - Drugs

2

Description
Control group: placebo solution was delivered to patients as a tube for two weeks for the case group. The atorvastatin group placed the atorvastatin paste in the maxilla denture 4 times daily after each meal after cleaning the denture with a toothbrush, and the denture did not come out until the next meal.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tooba Dental Clinic

Full name of responsible person
Mohammad ebrahimisaravi

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Tooba Dental clinic_ khazar Squer_beside Alimohammadi drug store_ Sari

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Sponsors / Funding sources

1

Sponsor

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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
80

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
Mohammad ebrahimisaravi

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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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
Because of no available data
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data were recruited from a private dental clinic
When the data will become available and for how long
after publication
To whom data/document is available
All people
Under which criteria data/document could be used
After recieing formal consent form from the authors
From where data/document is obtainable
corresponding author
What processes are involved for a request to access data/document
electronic request from corresponding
Comments