

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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 atorvastatin. 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

Atrovastatine 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

Country

Iran (Islamic Republic of)

Phone

+98 11 3321 0830

Email address

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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, corticosteroids in last one month allergy to Nystatine mouthwash patients with inappropriate seal and change in color Immunosuppressive 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 lesion

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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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

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

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Person responsible for updating data**Contact****Name of organization / entity**

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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 receiving 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