

# 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

mohammadebrahimisaravi@gmail.com

##### 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

**Street address**

Tooba Dental clinic\_ khazar Squer\_beside  
Alimohammadi drug store\_ Sari

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Sarahakbari1376@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mohammad Ebrahimisaravi

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Mohammadebrahimisaravi@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**

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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**Email**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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

Mazandaran University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Postal code**

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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**