

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Assessment of Atorvastatin mucoadhesive effect on minor recurrent aphthous stomatitis

#### Protocol summary

##### Study aim

evaluation of effectiveness of atorvastatin-containing mucoadhesive on recurrent aphthous stomatitis

##### Design

The clinical trial has a control group, with parallel groups, double-blind, randomized, phase 3. at first, based on the inclusion criteria, 44 people will be selected by available sampling method. Randomization of this study is done by blocking with random allocation software. Then the patients are divided into two groups such as 22 patients in the intervention group and 22 patients in the control group

##### Settings and conduct

The study population will be selected from those referring to the Department of Oral medicine, Dental school, Mazandaran University of Medical Sciences in 1400. Patients are asked to visit within the 24 hours after the outbreak. in the intervention group, 3 pieces of mucoadhesives will be given daily for 10 days so that they can use it in the morning, noon and night. Patients should abstain from eating and drinking for 30 minutes. In the control group, the same operation will be done with placebo. In order to assess the amount of pain and the healing, patients are examined on days 0, 3, 5, 7 to determine the size of the lesions and the inflammatory area. Patients also determine the severity of pain by VAS criteria. Participants and the examiner are not aware of the type of mucoadhesive used (atorvastatin or placebo)

##### Participants/Inclusion and exclusion criteria

Patients with recurrent aphthous stomatitis, ranging in age from 20 to 40 years, have all reported a history of minor ulcerations in the lips and buccal mucosa

##### Intervention groups

The atorvastatin is placed topically on the lesion and it is delivered to the inflamed area for a longer period of time. for comparison, the control group will receive placebo.

##### Main outcome variables

Atorvastatin-containing adhesive, pain, healing time,

wound inflammation

#### General information

##### Reason for update

##### Acronym

RAS

##### IRCT registration information

IRCT registration number: **IRCT20170430033722N4**

Registration date: **2021-07-16, 1400/04/25**

Registration timing: **retrospective**

Last update: **2021-07-16, 1400/04/25**

Update count: **0**

##### Registration date

2021-07-16, 1400/04/25

##### Registrant information

##### Name

Tahereh Molania

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3354 3861

##### Email address

tmolania@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-04, 1400/01/15

##### Expected recruitment end date

2021-05-05, 1400/02/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Assessment of Atorvastatin mucoadhesive effect on minor recurrent aphthous stomatitis

**Public title**  
Assessment of Atorvastatin mucoadhesive effect on minor recurrent aphthous stomatitis

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients with recurrent aphthous stomatitis showing aphthous lesions in the lips and buccal mucosa No systemic disease Do not take immunosuppressive drugs for the past month Do not use dentures Do not take antibiotics  
**Exclusion criteria:**  
Pregnant patients People who are not able to use mucoadhesive People with syndromes in which aphthous ulcers are manifestations (Behjat syndrome) the smokers People with autoimmune mucocutaneous lesions Patients with liver failure, myopathy and muscle problems Patients with allergies, hives and itchy skin and mucous membranes People who can not stay in the study due to personal or social reasons

**Age**  
From **20 years** old to **40 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
Target sample size: **44**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The samples will be determined by random blocking method with 4 blocks and using the random number table of Random Allocation Software. Blocking and allocation sequencing for concealment will be done by the person not involved in the research. The allocation ratio of the samples will be (Allocation 1: 1) and they will be placed in two groups receiving atorvastatin and placebo mucoadhesives. Drugs will then be given to patients based on the blocks obtained and in the order of allocation

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
participants are not aware of the type of mucoadhesive used the examiner (the person measuring the size of the lesions) is also unaware of the type of mucoadhesive used

**Placebo**

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**  
School of Dentistry, Mazandaran University of Medical Sciences, Sari, Khazar Square, next to Touba Complex  
**City**  
sari  
**Province**  
Mazandaran  
**Postal code**  
4815733971  
**Approval date**  
2021-01-05, 1399/10/16  
**Ethics committee reference number**  
IR.MAZUMS..REC.1400.8346

## Health conditions studied

**1**

**Description of health condition studied**  
Recurrent aphthous stomatitis

**ICD-10 code**  
K12.0

**ICD-10 code description**  
Recurrent oral aphthae

## Primary outcomes

**1**

**Description**  
The size of the erythematous halo around the aphthous lesion

**Timepoint**  
0 (Before intervention) and 3, 5 and 7 days after aphthous lesion

**Method of measurement**  
Metal caliber

**2**

**Description**  
Patients' pain intensity

**Timepoint**  
0 (Before intervention) and 3, 5 and 7 days after aphthous lesion

## Method of measurement

Visual Analog Scale (universal Pain Assessment Tool)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients will be given 3 mucoadhesives containing 10 mg of atorvastatin daily for 10 days to use in the morning, noon and night. This mucoadhesive is made in the laboratory of Sari School of Pharmacy. Patients are instructed in how to use the mucoadhesive so that it should be placed on the wet mucosa of the lesion and they should avoid eating and drinking for up to 30 minutes after use.

#### Category

Prevention

### 2

#### Description

Control group: Patients will be given 3 doses of non-drug adhesive (placebo) daily for 10 days so that they can use it in the morning, noon and night. This mucoadhesive is made in the laboratory of Sari School of Pharmacy. Patients are instructed in how to use the mucoadhesive so that it should be placed on the wet mucosa of the lesion and they should avoid eating and drinking for up to 30 minutes after use.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dental Clinic, Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr Tahereh Molania

##### Street address

Dental clinic, Khazar Blvd, Khazar square Sari Mazandaran

##### City

Sari

##### Province

Mazandaran

##### Postal code

4815733971

##### Phone

+98 11 3325 4134

##### Email

t\_molania117@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Majid Saeedi

##### Street address

Vice chancellor for research, The martyr Motahhari square, Street teacher

##### City

Sari

##### Province

Mazandaran

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##### Phone

+98 11 3448 4800

##### Email

SRC@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

Foreign

#### Category of foreign source of funding

Sponsor: country of origin

#### Country of origin

IR

#### 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

Maede Salehi Sarookolaei

##### Position

Oral Diseases specialist-Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

##### Street address

Sari dentistry college, Khazar square

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr Tahereh Molania

**Position**

Expert mouth disease diagnosis / Assistant Professor,  
Faculty of Dentistry University of Medical Sci

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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Dental clinic, Khazar Blvd, Khazar square

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr Tahereh Molania

**Position**

Expert mouth disease diagnosis / Assistant Professor,  
Faculty of Dentistry University of Medical Sci

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Dental clinic, Khazar Blvd, Khazar square

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**Postal code**

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**Web page address**

## 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