

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

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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

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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

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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

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

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Person responsible for scientific inquiries

Contact

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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

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Latest degree

Specialist

Other areas of specialty/work

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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