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

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Tahereh Molania

Name of organization / entity
Mazandaran University of Medical Sciences

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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 mucocutaneus 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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