

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Investigation the clinical efficacy of Colchicine-loaded polymeric nanofibers on aphthous ulceration, A Pilot Study

Protocol summary

Study aim

Investigating the clinical effect of nanofibers containing colchicine as an anti-aphthous drug

Design

A controlled, parallel-group, open-label, randomized, phase 2 clinical trial on 20 patients. Random allocation software will be used for randomization.

Settings and conduct

This clinical trial study will be conducted in order to evaluate the effect of polymeric nanofibers carrying colchicine in the treatment of oral thrush, on 20 patients hospitalized in Zaytoun Medical Complex in 1401-1402. The size of the lesion will be determined based on the maximum diameter of the wound by placing one-millimeter grid paper (transparent paper rulers that are marked as 1 mm units and are disposable). The patient's pain and burning sensation will be evaluated according to VAS, which is a line of 100 mm. Zero means no pain and 100 indicates the most pain the patient has experienced in his lifetime.

Participants/Inclusion and exclusion criteria

Inclusion Criteria : Age range between 20 and 40 years
No more than a day has passed since the beginning of aphthous ulcers
Not using another treatment method for your aphthous lesions before visiting
No history of known systemic disease associated with aphthous ulcers
Not having suspicious symptoms of systemic diseases related to aphthous ulcers
Exclusion Criteria : Recent use of colchicine
Using another drug simultaneously with the drugs prescribed to treat the pest
Not to use the medicine as recommended according to the patient's own statements
Failure to return the patient for re-examination
The presence of lesions in the area of the tonsils and the posterior 1/3 of the mouth
Concomitant use of immunosuppressive drugs
Lactating and pregnant women

Intervention groups

The intervention group includes group A (triamcinolone oral gel) or group B (nanofibers carrying the drug

colchicine).

Main outcome variables

Size of the lesion; pain and burning

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160920029889N4**

Registration date: **2023-01-07, 1401/10/17**

Registration timing: **prospective**

Last update: **2023-01-07, 1401/10/17**

Update count: **0**

Registration date

2023-01-07, 1401/10/17

Registrant information

Name

Afshin Shiva

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 4991

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-14, 1401/10/24

Expected recruitment end date

2023-06-14, 1402/03/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the clinical efficacy of Colchicine-loaded polymeric nanofibers on aphthous ulceration, A Pilot Study

Public title

Effect of Colchicine on aphthous ulceration.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range between 20 and 40 years No more than a day has passed since the beginning of aphthous ulcers Not using another treatment method for your aphthous lesions before visiting No history of known systemic disease associated with aphthous ulcers Not having suspicious symptoms of systemic diseases related to aphthous ulcers

Exclusion criteria:

Recent use of colchicine Using another drug simultaneously with the drugs prescribed to treat the pest Not to use the medicine as recommended according to the patient's own statements Failure to return the patient for re-examination The presence of lesions in the area of the tonsils and the posterior 1/3 of the mouth Concomitant use of immunosuppressive drugs Lactating and pregnant women

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

First, eligible patients will be selected non-randomized, sequential. Then these patients are coded using computer random allocation software, and then the codes are divided into two parts, and each part of the codes will be assigned to a group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not 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

Mazandaran University of Medical Sciences, Valie-Asr Boulevard

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2022-10-18, 1401/07/26

Ethics committee reference number

IR.MAZUMS.RIB.REC.1401.039

Health conditions studied**1****Description of health condition studied**

Aphthous

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes**1****Description**

Pain score

Timepoint

Before and 7 days after the start of treatment

Method of measurement

Visual Analogue Scale

2**Description**

Size of the lesion

Timepoint

Before and 7 days after the start of treatment

Method of measurement

Graph paper

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: A circular piece of polymer nanofibers with a diameter of 1.2 cm containing 1 mg of colchicine is prescribed to each patient and he will be taught to place the piece directly on the aphthous lesion without drying the mucous membrane of the wound. then it will be emphasized that the mouth should be open for two minutes and after connecting the nanofiber mat to the relevant surface, refrain from moving it with the help of the tongue so that the medicine is released slowly. This procedure is performed 3 times a day. The patient will be taught that if the mucous surface is dry before using the medicine, after placing the mat on the lesion, ensure that the mat is moistened. In addition, the medicine should be used after eating and avoid eating and drinking for an hour after that.

Category

Treatment - Drugs

2

Description

Control group: each patient will be given a package and will be taught to first dry the mucous surface of the wound slowly and then soak a small piece of sanitary cotton measuring about 3 x 3 centimeters with medicine and place it on the infected lesion. Then it will be emphasized that the mouth should be open for two minutes and perform this action 3 times a day. The patient will be taught to use the medicine after eating and to avoid eating and drinking for an hour after.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zeytoun Medical Center

Full name of responsible person

Mohammad bagher Maher

Street address

No 5, Zeytoun Center, Hassani Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Pedram Ebrahimnezhad

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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

Private

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

Hamed Morad

Position

Assisstant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Afshin Shiva

Position

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Person responsible for updating data

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Position

Researcher

Latest degree

A Level or less

Other areas of specialty/work

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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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available