Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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

Street address

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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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Imam Sajjad (AS) Hospital, Enghelab square, Shahid Motahari Ave.

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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
Assistant Professor

Latest degree
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Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

Contact

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Full name of responsible person
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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