Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Preparation and clinical evaluation of a novel colchicine mucoadhesive gel for the treatment of aphthous stomatitis: An experimental study and a double blinded randomized clinical trial

Protocol summary

Study aim

Preparation and clinical evaluation of a novel colchicine mucoadhesive gel for the treatment of aphthous stomatitis

Design

In this study, patients with aphthous stomatitis are selected through recall in pharmacies, physicians' offices and social networks according to the inclusion criteria and will enter the study after obtaining written consent. Patients' information including age, sex, weight, underlying diseases, and medications will be recorded. Patients using the RAND function of Excel software are randomly divided into two groups, including the colchicine group and the placebo group (basal posterior mucosa gel without colchicine) in each group of 25 people. Patients will use the drug twice a day at the rate of one drop per pest. At the beginning of treatment and after every 2 days for 10 days, the condition of aphthous lesions will be checked

Settings and conduct

A double-blind randomized controlled clinical trial in Yazd province on 50 patients in the control and intervention groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with aphthous stomatitis starting up to two days, No pregnancy and lactation, patients between 18_65 years old, No history of allergies to colchicine Exclusion criteria: Patients with skin diseases, Sensitivity to colchicine or any of components of the product, Do not use the drug for two consecutive days, Exacerbation of the aphthous stomatitis

Intervention groups

In the present study, patients will be divided into two groups: colchicine mucoadhesive gel receiving group، Base mucoadhesive gel receiving group.

Main outcome variables

Pain، inflammation، aphthous lesions size، number of aphthous lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191106045356N8**
Registration date: **2021-08-06, 1400/05/15**
Registration timing: **prospective**

Last update: **2021-08-06, 1400/05/15**
Update count: **0**

Registration date

2021-08-06, 1400/05/15

Registrant information

Name

Mohsen Zabihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3865

Email address

mzabihi100@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-21, 1400/05/30

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Preparation and clinical evaluation of a novel colchicine mucoadhesive gel for the treatment of aphthous stomatitis: An experimental study and a double blinded randomized clinical trial

Public title
Preparation and clinical evaluation of a novel colchicine mucoadhesive gel for the treatment of aphthous stomatitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with aphthous stomatitis starting up to two days Patient between 18-65 years old No pregnancy and lactation No history of allergies to colchicine

Exclusion criteria:
Patients with skin diseases Sensitivity to colchicine or any of the components of the product Do not use the drug for two consecutive days Exacerbation of the aphthous stomatitis

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is performed based on the RND function of Excel software and patients are divided into two groups A and B. The drug and placebo are uniform and coded in terms of the shape of the drug and the drug container, and the patient and the physician prescribing the drug and the evaluator do not know the composition and content of each drug container.

Blinding (investigator's opinion)
Double blinded

Blinding description
Different groups of drugs are placed in uniform and coded containers, and the prescribing physician and the evaluator do not know the composition and content of each drug container.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address
Alem sq.

City
Yazd

Province
Yazd

Postal code
۸۹۱۶۹۷۸۴۷۷

Approval date
2021-08-21, 1400/05/30

Ethics committee reference number
در حال دریافت کد اخلاق هستیم. لطفا دیگر ایتم ها را بررسی فرمایید. تا کد اخلاق صادر شودEthics committee of Shahid Sadoughi University of Medical Sciences

Health conditions studied

1

Description of health condition studied
Aphthous stomatitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Severity of pain

Timepoint
At the beginning of treatment and after every 2 to 10 days, the condition of aphthous lesions is evaluated for pain intensity (score 0 to 4).

Method of measurement
Scoring pain using a questionnaire

2

Description
Redness and inflammation

Timepoint
At the beginning of treatment and after every 2 to 10 days, the condition of aphthous lesions is evaluated for the severity of redness and inflammation (score 0 to 4).

Method of measurement
Scoring severe redness and inflammation using a questionnaire

3

Description
Total area of aphthous lesions
Timepoint
At the beginning of treatment and after every 2 to 10 days, the condition of the aphthous lesions is evaluated in terms of the total area of the aphthous lesions.
Method of measurement
Determining the total area of aphthous lesions through Fiji software

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Includes 25 patients selected from the city's pharmacies and randomly selected based on the RND function of Excel software. Patients will use the prepared drug twice a day (0.05% colchicine adhesive mucus gel) at the rate of one drop for each aphthous. At the beginning of treatment and after every 2 to 10 days, the condition of the aphthous lesions is evaluated in terms of pain intensity (score 0 to 4), total lesion area and intensity of redness and inflammation (score 0 to 4) and number of lesions.
Category
Treatment - Drugs

2

Description
Control group: Includes 25 patients selected from the city's pharmacies and randomly selected based on the RND function of Excel software. Patients will use one placebo twice a day (base glue-free mucosal gel without colchicine) at the rate of one drop per aphthous. At the beginning of treatment and after every 2 to 10 days, the condition of the aphthous lesions is evaluated in terms of pain intensity (score 0 to 4), total lesion area and intensity of redness and inflammation (score 0 to 4) and number of lesions.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Drug stores
Full name of responsible person
Dr. Mohsen Zabihi
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8916978477
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Masood Mirzaei
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City
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Province
Yazd
Postal code
Phone
+98 35 3726 3733
Email
dvc.research@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Yazd University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
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
Yazd University of Medical Sciences
Full name of responsible person
Dr. Mohsen Zabihi
Position
Professor
Latest degree
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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