

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 ایتیم ها را بررسی فرمایید.
Ethics 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

Street address

Alem sq.

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 3820 3419

Email

mzabihi100@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Masood Mirzaei

Street address

Bahonar sq.

City

Yazd

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

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Alem sq.
City
Yazd
Province
Yazd
Postal code
8916774520
Phone
+98 35 3820 3865
Email
mzabihi100@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Mohsen Zabihi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Alem sq.
City
Yazd
Province
Yazd
Postal code
8916774520
Phone
+98 35 3820 3865
Email
mzabihi100@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr. Mohsen Zabihi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Alem sq.
City
Yazd
Province
Yazd
Postal code
8916774520
Phone
+98 35 3820 3865
Email
mzabihi100@gmail.com

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